POTOMAC INSTITUTE
FOR POLICY STUDIES

NEUROTECHNOLOGY FUTURES STUDY

A Roadmap for the Development of
Neuroscience and Neurotechnology
that will Lead to the Economic Revolution
of the 21st Century

**The brink of the greatest
discovery in mankind's history:
THE WORKINGS OF THE HUMAN BRAIN**

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A POTOMAC INSTITUTE FOR POLICY STUDIES REPORT

NEUROTECHNOLOGY FUTURES STUDY

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LIST OF ACRONYMS

3-D	Three Dimensional
ACLU	American Civil Liberties Union
ADA	Americans with Disabilities Act
ADHD	Attention Deficit/Hyperactivity Disorder
BAA	Broad Agency Announcement
BIRN	Biomedical Informatics Research Network
CIA	Central Intelligence Agency
CNS	Central Nervous System
CNS	Center for Neurotechnology Studies
CPS	Calculations per Second
CT	Computed Tomography
DARPA	Defense Advanced Research Projects Agency
DBS	Deep Brain Stimulation
DoD	Department of Defense
DOE	Department of Energy
EEG	Electroencephalogram
ELSI	Ethical, Legal and Social Issues
EPPA	Employment Polygraph Protection Act
ESCRO	Embryonic Stem Cell Research Oversight (Committee)
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
fMRI	Functional Magnetic Resonance Imaging

HIPAA	Health Insurance Portability and Accountability Act
IDEA	Individuals with Disabilities Education Act
I/O	Input/Output
IRB	Institutional Review Board
IT	Information Technology
MEG	Magneto encephalography
MEMS	Microelectromechanical Systems
MRI	Magnetic Resonance Imaging
NAS	National Academies of Sciences
NIA	Neurotechnology for Intelligence Analysts (DARPA Program)
NIH	National Institutes of Health
NIO	Neurotechnology Industry Organization
NNI	National Nanotechnology Initiative
NSF	National Science Foundation
PET	Positron Emission Tomography
PTSD	Post Traumatic Stress Disorder
R&D	Research and Development
RFID	Radio Frequency Identification
RFP	Request for Proposal
S&T	Science and Technology
VA	Veterans Administration

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I. PREFACE

The Potomac Institute for Policy Studies was created to address the most important science and technology policy questions of our time. A very large part of this mission has always been dedicated to analyzing the trends and developments in science and technology with potential to change human affairs in major ways. Clearly, a growing understanding of the brain and its functions may change every fiber of our existence to include the ways we learn, relate to each other, treat disease and injury, and perhaps even what it means to be human.

The Institute initially began the study of neuroscience and neurotechnology before the turn of the 21st century. We identified major developments in the field, which along with nanotechnology, advanced biotechnology, and information technologies, were viewed as the fields most likely to significantly affect humanity over the next twenty years. We advanced our analysis of neuroscience and neurotechnology through a focused assessment that began in 2005.

During this effort the Institute conducted five workshops, ten seminars, and interviewed and talked with more than 220 scientists at over 100 institutions. This work cumulated in a 2007 report that has been updated herein. Since 2007, the Institute has continued to actively follow, assess, document, and comment on the growth of neuroscience and neurotechnology through the activities of our Center for Neurotechnology Studies (CNS).

CNS has hosted and participated in hundreds of seminars and forums devoted to these sciences and technologies. The Center has contributed over 50 major works to international scholarly literature, provided lectures and testimony at a variety of national and international academic and governmental institutions, and is considered a leading voice in the study of neuroscience, neurotechnology, and the ethical, legal, and social issues (ELSI) generated by the development of these fields.

This document is a summation of over a decade of study, analysis, and publication. It outlines the key trends in neuroscience and neurotechnology and recommends a roadmap for investment that we believe will achieve the best possible future for humankind.

We would like to thank the key authors listed in the report as well as those who have participated in our seminars and forums and have contributed to the development of this body of thought. We would also like to thank Dr. Robert Hummel, Ms. Faith MacDonald and Mr. Patrick Cheetham for their tireless efforts over many years on this endeavor. We would also like to thank Ms. Sherry Loveless for editing, formatting, and publishing this report.

Michael S. Swetnam
CEO & Chairman
Potomac Institute for Policy Studies

II. EXECUTIVE SUMMARY

The Potomac Institute for Policy Studies undertook the Neurotechnology Futures Study to anticipate the path of future development of neurotechnology,[1] and to develop a strategic plan to advance the progression of this technology. The Potomac Institute also examined the potential ethical, legal and social issues that may arise as the technology develops, and considered approaches to be prepared for and mitigate these concerns.

The study group found that neurotechnology is a rapidly advancing field, with potential impacts that could far surpass those of the information revolution, the pending biotechnology revolution, or the anticipated nanotechnology revolution. The study concluded that targeted Federal government investment in a few key areas could play a significant role in developing and furthering the neurotechnology revolution.

The study group developed a technology investment Roadmap, which outlines the key research areas and technologies that will be needed to move neurotechnology forward. The Roadmap is divided into two main tracks (Figure 1). The first is fundamental science, or scientific discovery and understanding of the brain and cognition. The second is the development of technology and applications, which will feed back into scientific discovery and into the development of products and applications for medicine, the military, and the public. Each thrust has four key investment tracks that are described below.

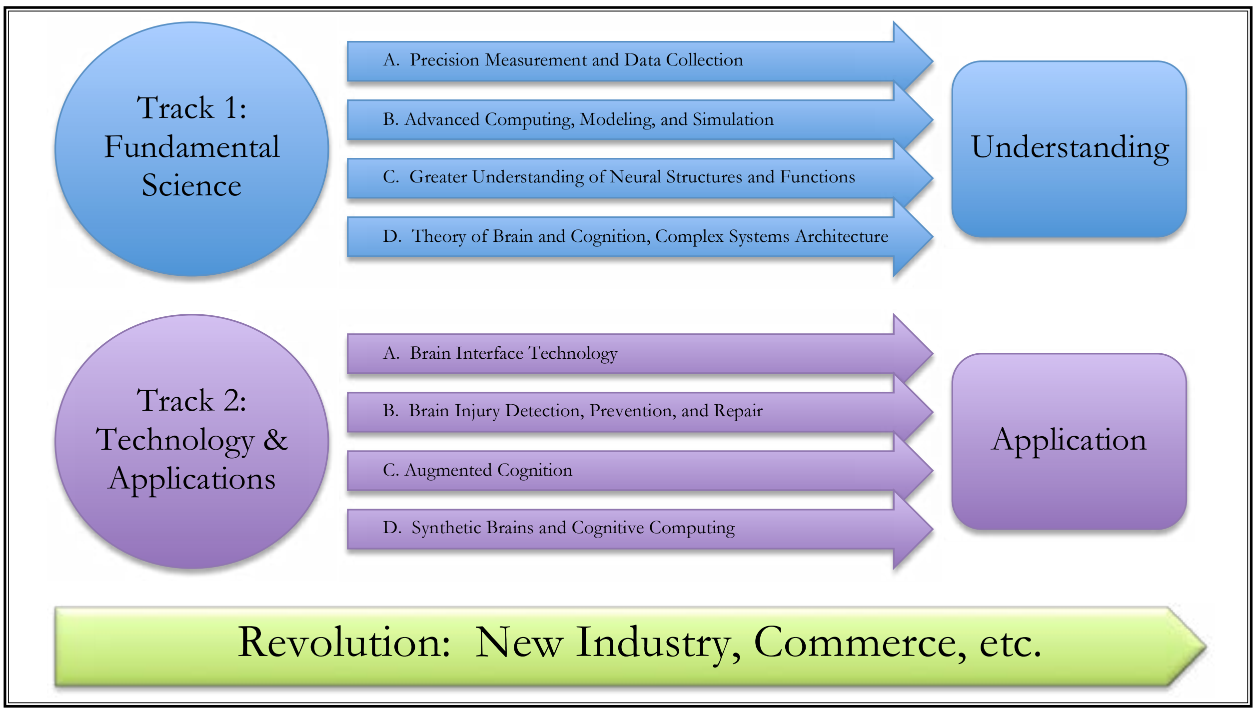

Figure 1: Roadmap for the Future of Neurotechnology: Concurrently pursued Tracks in Fundamental Science and Technology and Applications will together lead to a Neurotechnology Revolution.

1. Neurotechnology can be defined as any technologies used to investigate, modulate, repair, or improve the nervous system and its functioning. Technologies based on the functioning of the nervous system, such as cognitive computing, modeling and simulation tools, and data collection tools, are also essential components of neurotechnology.

Track 1: Fundamental Science

A. Precision Measurement and Data Collection

Progress in the field is being restricted by a lack of high resolution data. Although the number and capability of centers dedicated to various types of neuroimaging are increasing, greater access to high resolution machines and a process for sharing the collected data will significantly move our understanding of neurological processes forward. Further, the application of signal processing techniques to neuroscience research, and development of new and shared computing and analysis tools will vastly improve our understanding of the collected data.

To address this issue, we recommend that the Federal government invest in focused efforts to develop new data collection and analysis tools and support data standardization and dissemination. These aims would be supported by forming advanced research centers that would become interdisciplinary, focused centers for neurotechnology research. Partnerships with the National Science Foundation (NSF), National Institutes of Health (NIH), Veterans Administration (VA), the Department of Defense (DOD), and other agencies and research institutions would advance these goals.

B. Advanced Computing, Modeling and Simulation

Modeling and simulation of the brain, with the aim of developing a multi-scale, integrated model of the brain and cognition, will aid in our understanding of how the brain functions, from the level of individual neuron communications to cognition.

C. Greater Understanding of Neural Structures and Functions

Further research on brain function and architecture will be needed to advance neurotechnology applications. The ability of neurotechnology to interact with brain will be limited until functional areas of the brain are mapped with greater accuracy, communications within the brain are decoded, and processes such as neurogenesis and plasticity are more thoroughly understood. Research into neurogenesis has great potential to transform neuroscience and medicine, and should be pursued with a focused funding effort.

Again, partnerships between with NSF, NIH, VA, DOD, and others will be needed for research in learning, cognition, neurodevelopment, plasticity, and neurogenesis, since these areas go far beyond a single agency's mission and capabilities.

D. Theory of Brain and Cognition, Complex Systems Architectures

Improved understanding of biological information processing, cognitive patterns, and the complex systems architecture of the brain that subserves cognition will change both our understanding of human cognition and behavior, and will have a major impact on other fields, to include computing and robotics.

Track 2: Technology and Applications

A. **Brain Interface Technology**

Brain interface technology will be key to future applications that rely on information traveling between the brain and external tools. Relevant government entities should fast-track development of brain interface technologies; this technology would benefit medicine immediately, and would open up vast possibilities for future neurotechnologies.

B. **Brain Injury Detection, Prevention and Repair**

The repair of brains that have been damaged due to injury or disease is one of the key aims of neuroscience and neurotechnology. This aim appears achievable in the future, but will depend on improved understanding of the brain's mechanisms and how we can interact with them to promote repair. New tools developed in imaging, data collection and more precise interventions will have a revolutionary impact on neuroscience and the treatment of injury and disease.

C. **Augmented Cognition**

First steps toward augmented cognition are likely to include non-invasive devices that complement or supplement human capabilities, such as tools for learning and training augmentation, improved user interfaces based on neurocognitive principles, advanced assistive devices for the disabled, feedback mechanisms that give a user immediate information on the state of their performance, and much more. Use of physically-connected devices for augmentation may lie farther ahead, and will depend on advances in brain interfacing and greater understanding of brain function and signals.

D. **Cognitive Computing and Synthetic Brains**

The fields of computer science and neuroscience are increasingly feeding into the other's discoveries. Greater understanding of cognitive processes and patterns could have a revolutionary impact on computing, and advances in computational power and simulation tools are having a major impact on the practices of neuroscience.

Neurotechnology: Ethical, Legal and Social Issues (NELSI)

Neurotechnology has the potential to generate major ethical, legal and social issues – what we have termed NELSI – and these must be considered early on in the research and development (R&D) process. The goal is not to prevent R&D, but rather to define possible benefits, burdens, risks and problems, enable preparedness, and preclude potentially negative effects. Several neurotechnologies have already fostered concerns within the professional and public spheres, and will require immediate consideration, including deception detection, remote or undetected neuroimaging capabilities, stem cell research related to neurotechnology applications, and brain interface technologies. Overall, potential issues of neurotechnologic research and use include: safety and security, privacy and civil liberty concerns, potential misuse in the judicial system by employers or insurance companies, public fear of government abuse, and perceptions that the technology will be used to "read thoughts" or "mind control." More general issues will include where to draw the line between treatment and augmentation, whether augmentation, enablement and enhancement are ethically or socially acceptable, what the relationship between humans and computers might be in the future, equity and access of individuals to future technologies, and consideration of neurotechnologies' effect on the fundamental essence of the mind and what it means to be human.

Neurotechnologies with Immediate ELSI Concerns

- **Deception Detection**
- **Remote/Covert Imaging, Civil Liberties, and Human Rights**
- **Stem Cell and Neurogenesis Research**
- **Brain Interface Technologies**

NELSI Concerns

- **Individual Privacy and Civil Liberties**
- **Safety and Security**
- **Inadvertent use/Misuse of Neurological Information**
- **Employment Bias/Discrimination**
- **Government Employment Selection**
- **Misappropriated Law Enforcement and Intelligence Collection**
- **Judicial Misuse of Neurotechnology**
- **Fear of Government Abuse**
- **Mind Control**
- **Neuroweapons**
- **Treatment versus Augmentation**
- **Augmentation, Enablement and Enhancement**
- **Human-Computer Interaction and Sentient Machines**
- **Equity, Fairness, Distribution and Access**
- **Individuality, Free Will, and the Fundamental Essence of the Mind, and What Constitutes Normality, and the Human Being?**

Figure 2: List Outlining major technologies and potential NELSI issues.

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Recommendations: Research Initiatives

- Create a focused investment on critical neurotechnology areas of the Roadmap.
- Develop neurotechnology "Grand Challenges."
- Create new programs to:
  - Build regional neurotechnology imaging and signal decoding centers, support networking and data-sharing between multiple sites;
  - Develop a new generation of signal collection devices and technologies, to understand and decode brain signaling;
  - Develop new imaging and data collection technologies;
  - Understand and exploit neurogenesis and plasticity;
  - Build multi-scale models of brain function; and
  - Fast-track the development of brain interface technologies- develop new brain signal input/output (I/O) devices with greater scope and function (extending and refining technologies like deep brain stimulation, neuromodulators).
- Fund interagency research in learning and cognition, neurodevelopment, and plasticity.
- Fund interagency research on cognitive systems architecture of the brain.
- Fund an effort to establish a national repository for neuroscience data.
- Establish a National Neurotechnology Initiative to coordinate Federal efforts in developing neurotechnology and provide funding for NELSI research and guidance.

NELSI Recommendations

NELSI concerns are best addressed by taking proactive steps to establish internal structures, work with outside experts, and form partnerships between agencies to prepare for and deal with potential issues surrounding neurotechnology. A framework of ethical and legal guidelines for future research and oversight mechanisms (similar to Institutional Review Boards and Data Monitoring Committees) to ensure appropriate research and use of neurotechnologies is needed. A Federal-level Neurotechnology Coordination Office should include devoted professional staff (or contractors) for NELSI, and set-aside funding for NELSI in program or office budgets. Formation of a National Neurotechnology Initiative would also benefit this effort. As in the Human Genome Project and the National Nanotechnology Initiative, Federal research efforts would be focused on the specific ethico-legal and social issues generated by various types and trajectories of neurotechnologic research and use, ensuring careful consideration of these issues and sharing responsibility across all the agencies developing neurotechnology.

Key recommendations include:

- Take immediate steps to define and address ethical, legal and social issues arising from realistic assessment of neurotechnological capabilities and near-term developments.

- Work with outside experts and form partnerships with other agencies to prepare for and deal with potential issues.

- Develop ethics policies and standards for research and applications of neurotechnologies, including procedures for ethical review of study design and research objectives, especially for immediate, volatile issues like deception detection (lie detection), prediction of behavior, determination of culpability, and stem cell research.
- Set aside funding for NELSI, including devoted professional staff (or contractors), following the Department of Energy (DOE), NIH, Human Genome Project models of directed funding for research studies and staff hours devoted to ELSI.
- Focus early neurotechnology efforts on short-term goals and prevent over- and/or under-stating of objectives or technical possibilities.
- Carefully construct a communications and public education strategy to mitigate neurotechnology-related ethical, legal, social, and political issues, and to engage civil-libertarians, legal experts, and ethics' scholars.
- Afford ongoing education and communication of research approaches and findings to legislators and the public as essential to addressing and mitigating potential concerns.
- Support a review of existing national and international protections and laws for neurotechnology applications, including civil liberties, medical information, employment, discrimination, guarantees of privacy, federal regulation of devices, etc.
- Participate in developing model policies and procedures for R&D and appropriate use of neurotechnology, in consultation with outside experts, professional societies and government agencies.
- Facilitate or advocate the creation of oversight mechanisms for ethically responsible development of neurotechnologies.

II. BACKGROUND

Study Objectives

The Potomac Institute for Policy Studies undertook the Neurotechnology Futures Study to:

- **Develop a Roadmap for the progression of neurotechnologies;**
- **Identify potential Federal government investments that could significantly change or advance the progression of neurotechnologies; and**
- **Identify and analyze the potential social and political implications of these technologies and consider mitigating strategies.**

As neurotechnology advances it is appropriate to ask what role the Federal government should play in such development. What are the inflection points that the Federal government can leverage to aid in the growth of this scientific field? What are the critical investments that the Federal government can make to expedite the development of new technologies, and ensure that the United States has the capabilities necessary to remain globally competitive? And, how can the ethical and social issues associated with this technology be addressed?

In this study, the Potomac Institute developed a Roadmap for neurotechnologies, identified key investments and technical challenges, and analyzed potential future applications of these technologies. The study group also attempted to identify and evaluate the potential ethical, legal and social impacts of this emerging technology, and provide recommendations for addressing these issues.

Findings

Through extensive research and the sponsorship of regional workshops, the Potomac Institute study team gathered a comprehensive picture of the state of the field and how research and technology needs could be met. The major points outlined below are based on consensus views from the workshops as well as the study group's research. Findings on the needs of the field informed the Neurotechnology Roadmap, and recommendations for the investment strategy.

- **Neuroscience is advancing more rapidly than any other science today.**

  Brain research is moving forward more rapidly than any other science today. Recent discoveries are revolutionizing our understanding of the human brain, and new applications are emerging almost daily. Several advances in genetics, neurochemistry, neurobiology and cognitive computing are rapidly increasing our understanding of the structure and function of the brain. When combined with sensing and imaging capabilities, such as advanced forms of electroencephalography (EEG), including quantitative EEG (qEEG) and magnetoencephalography (MEG), positron emission tomography (PET) and single photon emission computerized tomographic scans (SPECT), functional magnetic resonance imaging (fMRI), and diffusion tensor imaging (DTI), these advances have facilitated identification of neural structures and activities associated with cognitive processes. In short, we are beginning to understand the processes associated with thought and cognition. At the same time, new technologies are emerging in clinical research that allow direct, advanced interaction with the brain itself. Such technologies include ever more sophisticated forms of brain implants- e.g., deep brain stimulation (DBS), transcranial magnetic stimulation (TMS), neuroprosthetics and neuro-orthotics, neurogenetic and neural tissue transplants, more specialized types and forms of neuropsychopharmacological agents, and the use of nanotechnology to facilitate these and other techniques and technologies that access and affect the micro- and macro-structure and function of the brain. (See Table 1, below).

Assessment Technologies
- **Neuroimaging and sensing**
- **Neurogenomics and genetics**
- **Neuroproteomics**

Intervention Technologies
- **Novel pharmaceuticals**
- **Brain implants**
- **Transcranial stimulators**
- **Brain-machine interfaces**

TABLE 1: CATEGORIES AND TYPES OF CURRENT NEUROTECHNOLOGIES.

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Current research in neurotechnology is primarily focused on clinical applications, with the exception of the Department of Defense's (DoD) research on intelligence applications, and some commercial ventures into lie-detection and medical devices. Much of defense spending related to neurotechnology is also focused upon clinical applications, such as enhanced prediction, diagnostics, prosthetics and therapy for brain-injury. The major clinical areas are being addressed by Federal funding agencies such as the National Institutes of Health (NIH) and its sub-agencies, the National Science Foundation (NSF), the Veterans Administration (VA), and others.

Neurotechnology is also engaging the private and academic sectors as part of a number of dedicated triple-helix initiatives (of government, academic and commercial collaboration).[2] There are more than 50,000 neuroscientists publishing in more than 300 journals worldwide, and the field draws on experts from many other fields. Using the examples of progress in neuroimaging and deep brain stimulation respectively, the field has had greater than 70% growth during the 10 year period from 2000-2010, as evidenced by the increased number of studies reporting basic and translational research and clinical applications of neurotechnology depicted in Figures 3-4.[3]

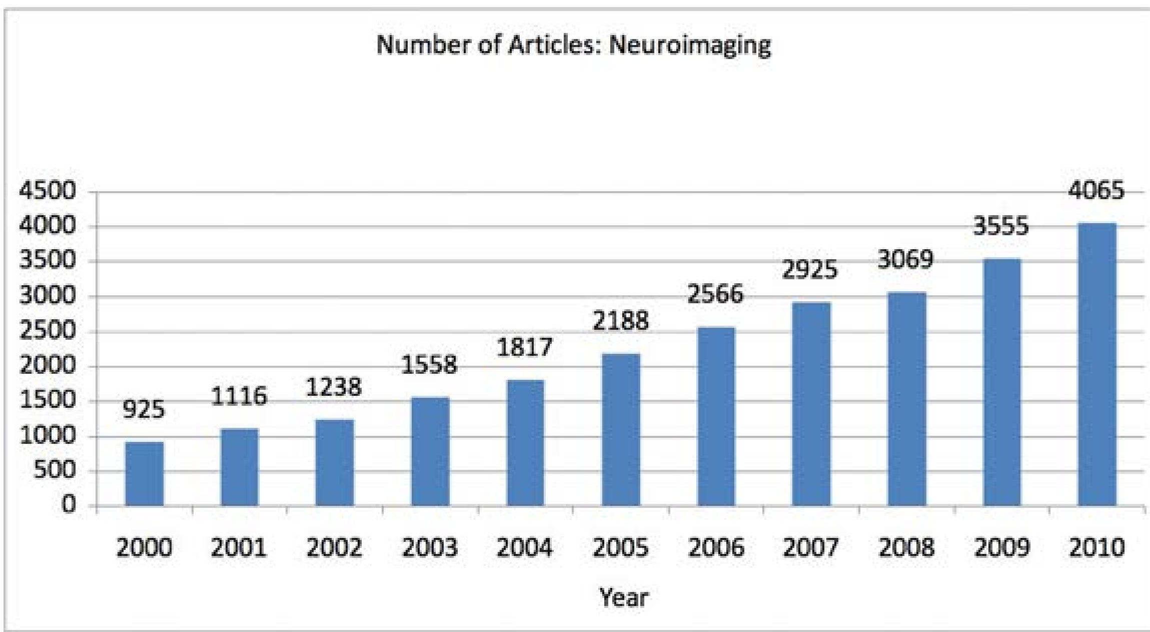

FIGURE 3: THE NUMBER OF ARTICLES PUBLISHED IN NEUROIMAGING OVER THE LAST DECADE HAS SIGNIFICANTLY INCREASED.

2. (a) Giordano J. On the necessity for ethics and policy in the scientific and technologic education of medical professionals. *BMC Medical Education.* 2013; 12. (b) Wurzman R. Inter-disciplinarity and constructs for STEM education: At the edge of the rabbit hole. *Synesis: a Journal of Science, Technology, Ethics and Policy.* 2010; 1:32-35.

3. Giordano J. Neurotechnology as demiurgical force: Avoiding Icarus' folly. In: Giordano J. (ed.) *Neurotechnology: Premises, Potential and Problems*. NY: CRC Press, 2012, p. 1-14.

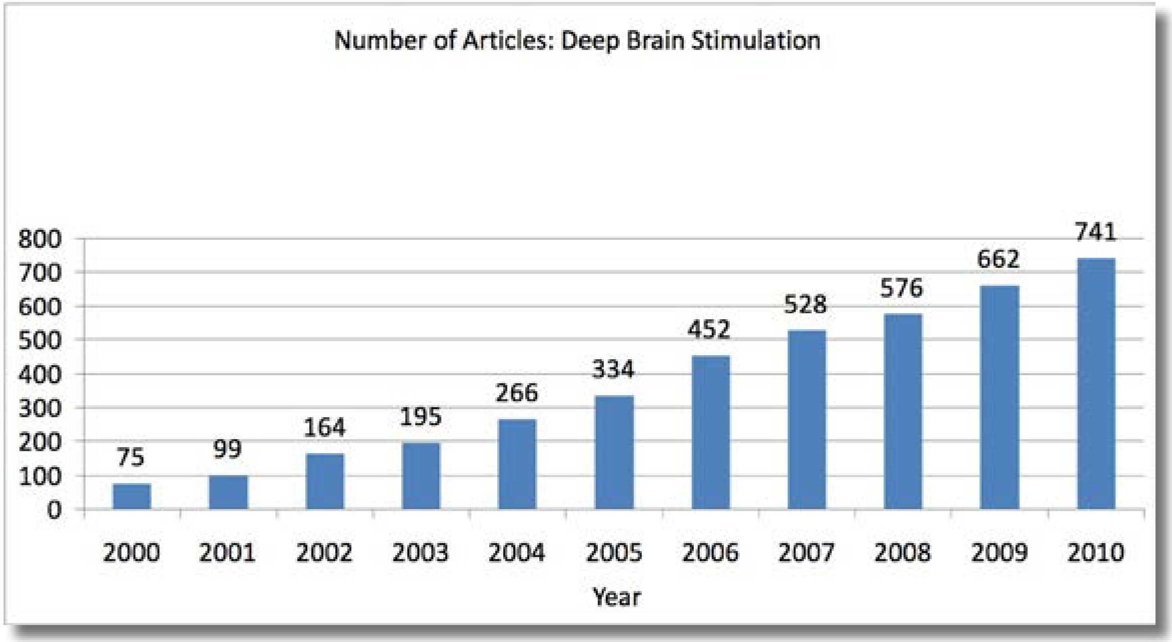

FIGURE 4: A SIGNIFICANT INCREASE IN THE NUMBER OF ARTICLES PUBLISHED REGARDING DEEP BRAIN STIMULATION IN A TEN YEAR PERIOD.

The market research firm NeuroInsights, which is dedicated entirely to emerging technology companies and venture capital, estimates that the neurotechnology industry, including drugs, devices and diagnostics, reached $158.6 billion in revenues with 5.6% growth in 2011 compared to $150.1 billion and 5.0% growth in 2010.[4] As a direct result of this exponential accretion in the last few years, the Neurotechnology Industry Organization (NIO) was recently formed to represent the industry's interests.[5]

- **U.S. Government funding of Neurotechnology Research and Development is modest.**

U.S. Government funding of neurotechnology is very modest when compared to the estimated global neurotechnology industry, and government efforts in nanotechnology and the biological sciences. The total government effort in neurotechnology is about $200 million, and is dispersed across the Department of Defense (DARPA and the Services), NSF, and NIH. In comparison, nanotechnology spending totals approximately $1.8 billion for the National Nanotechnology Initiative.

Federal Government funding leadership in digital, nanotechnology, and biological sciences would suggest that similar focused funding efforts would significantly advance the development of neuroscience and technology (S&T), and this investment will clearly play a key role in the development of this field.

4. NeuroInsight. "The Neurotechnology Industry 2012 Report." August 2012.
5. Neurotechnology Industry Organization. "About the NIO." Accessed Jan. 30, 2007. http://www.neurotechindustry.org/aboutnio.html.

- **The potential impacts of neurotechnology could surpass those of the digital revolution.**

  The potential impact of the neurotechnology revolution may far surpass that of previous technology revolutions. Our studies have shown that while past revolutions in industrial and digital technology provided new tools, neurotechnology will change the way we use tools altogether, and will significantly change society in ways that can barely be imagined.[6] We have also shown that this revolution will also have a major impact on future warfighting capabilities, and the U.S. Government and military must not be left behind in this revolution.[7]

  The two sciences of cognitive computing and cognitive neuroscience can be expected to develop reciprocally and synergistically. The next generation of computing technology will be closely related to the development of neurotechnology. Researchers are seeking ways to simulate the cognitive processes and patterns of the brain in computer architectures and systems. This pursuit will continue to benefit from increased understanding of neurological systems and processes.

  The field of cognitive neuroscience is benefitting from this revolution in technology. Functional neuroimaging is changing the understanding of the neural bases of cognition and behavior. Advanced computing systems are helping to understand and interface with the brain. Several projects currently underway in academia and government seek to develop brain-computer interfaces that send and receive information and could enhance human ability to perform mental and physical tasks. Projects are underway that seek to use brain signals to drive a variety of prostheses and external devices, including robots. Other projects seek to use cognitive processes in the brain to enhance human recognition of complex imagery. Other projects are aimed at simulating or restoring the operation of the hippocampus, which functions in the processing and storage of memory. Other disciplines, such as signals analysis, advanced simulation, nanotechnology devices and mathematical modeling, will all have a significant effect on the development of this new technology revolution.

  Taken together, we have shown that the rapid and convergent advancements in these fields support the potential for a neurotechnology revolution in the near future.[8] The nature of this revolution, and how the technology emerges in both highly specialized areas and everyday life, will depend on who takes a leadership role in shaping it. In this study we outline how the Federal government should continue to invest in and shape the emerging field of neurotechnology.

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6. Benedikter R, Giordano J: The outer and inner transformation of the global sphere through technology: The state of two fields in transition. *New Global Studies.* 2011; 5(2).
7. (a) Giordano J, Wurzman R. Neurotechnology as weapons in national intelligence and defense. *Synesis: A Journal of Science, Technology, Ethics and Policy.* 2011; 2:138-151. (b) Giordano J, Forsythe C, Olds J. Neuroscience, neurotechnology and national security: The need for preparedness and an ethics of responsible action. *AJOB-Neuroscience.* 2010; 1(2):1-3.
8. (a) Giordano J. Integrative convergence in neuroscience: Trajectories, problems and the need for a progressive neurobioethics. In: Vaseashta A, Braman E, Sussman P. (eds.) *Technological Innovation in Sensing and Detecting Chemical, Biological, Radiological, Nuclear Threats and Ecological Terrorism.* (NATO Science for Peace and Security Series), NY: Springer, 2012. (b) Giordano J, Benedikter R. An early - and necessary - flight of the Owl of Minerva: Neuroscience, neurotechnology, human socio-cultural boundaries, and the importance of neuroethics. *J. Evolution and Technol.* 2012; 22(1):14-25.

- **Ethical, Legal and Social Issues must be considered early on.**

  As neurotechnology develops, the impacts of this technology on our society will need to be considered. In general, technology that enables the prevention or reduction of disability and suffering caused by neurological and psychiatric conditions will likely be accepted as beneficial to society. However, here too issues arise as to the limits of intervention, what constitutes treatment, enablement, or enhancement, and who shall receive these technologies and services. As well, other technologies that can be used to access and control the brain, to vastly increase the ability to access large amounts of data or even reason and think at increased capacities, will affect society in ways that are yet unforeseen. It is clear that these technologies will have profound effects on humanity. The societal impacts of neuroscience and neurotechnology must be addressed and analyzed in order to prepare for their potential use or misuse – both at present and in the near future. In particular, scientists that develop these technologies should be involved in considering their potential uses and effects. We have been actively committed to studying, addressing and analyzing the ethico-legal and social issues spawned by emerging neurotechnologies, and have developed a groundwork for this NELSI project.[9] Section IV, "Ethical, Legal and Social Issues," presents the major issues in the near and middle terms, and outlines steps that can be taken to prepare for and mitigate them.

9. (a) Giordano J, Olds J. The interfluence of neuroscience, neuroethics and legal and social issues: The need for (N)ELSI. *AJOB-Neuroscience*. 2010; 2(2):13-15. (b) Giordano J. Neuroethics: Traditions, tasks and values. *Human Prospect*. 2011; 1(1):2-8.

III. THE ROAD MAP

Neurotechnology can be defined roughly as any technologies used to investigate, modulate, repair, or improve the nervous system and its functioning. Technologies based on the functions of the nervous system, such as cognitive computing, modeling and simulation tools, and data collection tools, are also essential components of neurotechnology.

The neurotechnology road map consists of two concurrently pursued tracks, as illustrated in Figure 5 below: (1) a theoretical science route, and (2) a supportive, but in its own right highly evocative, technological course. As suggested below, simple, incremental evolution left to its own devices will most certainly reveal mutual reinforcement of the two unfolding paths. However, revolutionary change, the result of strategic acceleration of the two trajectories aimed at medical as well as augmentative application, will far surpass the progress that would be produced by only medically-related incentives.

The need to repair or preserve the integrity of neural tissue certainly provides the entrepreneurial and ethical motivation to drive progress, and is already producing developments in neurotechnology. But the incentives represented by enhancing the functioning of nervous systems (i.e., not just tissue) – to think faster and better in an increasingly competitive, adversarial, and deadly environment – far exceed the "restorative-only" motif. If medical incentives are multipliers, brain augmentation incentives are exponents. In order to understand these opportunities, we portray each of the two threads suggested – science and technology – as sinews of each incentive system.

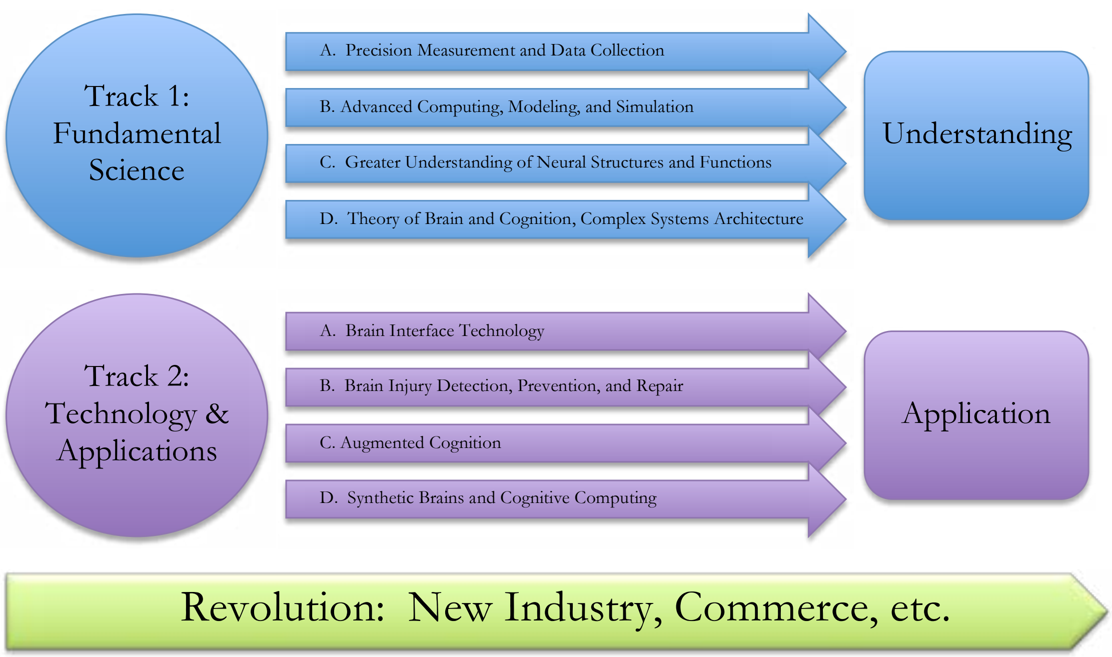

Figure 5: Roadmap for the Future of Neurotechnology: Concurrently pursued Tracks in Fundamental Science and Technology and Applications will together lead to a Neurotechnology Revolution.

Tremendous progress has been made in the sciences and technologies that form this fledgling enterprise, and payoffs have accrued, especially in medicine. Incremental advances will continue to occur evolutionarily through sensible investments as they are indicated by needs, particularly of medicine.

Game-changing, revolutionary breakthroughs, on the other hand, will rely on the development and exploitation of: (1) paradigmatic advancement of a basic understanding of the brain, and, necessarily; and (2) the development of brain-instrument interface technology that will support the capability to observe overt behavior and its corresponding brain activity, resolved sufficiently in space and time, and the capability to stimulate the brain with equally sufficient resolution. Together, the combined capability will for the first time provide (3) a complete closed-loop capability for selectively observing and manipulating behavior from the molar, down to any required neuronal level, in real time.

As implied, the necessary science and its requisite technology are closely integrated. In fact, progress in theory and incremental improvements in instrumentation progress cyclically. This appears to be especially evident in the case of neurotechnology. For example, increased insight into neural function generates new requirements for observing, measuring, and recording brain activity, which in turn imply requirements for novel technologies that can exploit modes and spectra of useful energy (e.g., electrical, nuclear). Invariably, improved observation supports the derivation of better theory, and importantly, not just further reductionism. The game-changing explosion cited in the paragraph above nonetheless requires significant advancements that will not necessarily be stimulated by the needs of clinical medicine. Moreover, our analysis of the directions in which neurotechnology could – and should – generate substantial progress for repair and augmentation imply successful achievement of specifiable, measurable goals. These are enumerated in the pages that follow.

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Track 1: Fundamental Science

Key elements of fundamental science that must advance to feed the overall development of neurotechnology are broken down into four tracks:

A. **Precision Measurement and Data Collection;**

B. **Advanced Computing, Modeling and Simulation;**

C. **Greater Understanding of Neural Structures and Functions; and**

D. **Theory of Brain and Cognition, Complex Systems Architectures.**

Each of these tracks will play an integral role in the development of neurotechnology, and should be pursued concurrently, not in isolation.

The needs in fundamental science include developing new tools for research and gaining greater understanding of the brain and cognition. First steps include transitioning technology from medical to other applications, and the development of higher-resolution – and new – tools that are outside the scope of usual medical technology. Systematic evaluation of neuroscientific and neurotechnologic heuristics have shown that the development and use of new technologies (e.g., fMRI; MEG) and analysis methods (i.e., signal processing) have great potential to expand understanding of brain activity, and will aid in development of more advanced technologies and a broader palette of applications.[10]

Goals over the longer term, which mesh closely with the goals of the field as a whole, are to gain deeper understanding of neuroscience, including brain structure, function and cognition. Immediate needs in this area include understanding processes such as neurogenesis and plasticity that could someday be harnessed for brain repair and other applications. Other analysis tools include modeling and simulation that, in combination with greater integration between fields like neuroscience, computing, and cognitive psychology, will lead to building a unified model of the brain.

A. Precision Measurement and Data Collection

Priority needs in the field of neurotechnology are higher spatial and temporal resolution of data, new tools and techniques for imaging and data collection, standardized data formats, data-sharing, and interdisciplinary research. These needs can be addressed in the short term by the application of new techniques to improve existing data and collection capabilities, and in the long term by development of higher-resolution tools and entirely new modalities. They will also require a major increase in interdisciplinary and cross-institutional research and sharing of resources and data, which would be enabled via Federally-funded centers of neurotechnology research.

10. Giordano J. (ed.) *Neurotechnology: Premises, Potential and Problems.* NY: CRC Press, 2012.

- **Neuroscience has a great need for higher temporal and spatial resolution in data collection and imaging tools.**

  Currently there is insufficient resolution in neuroimaging and an inability to measure the brain in enough detail to fully understand complex processes of communication and cognitive function. Existing data collection instruments have developed as a result of clinical needs, and are designed for these purposes. Most current brain scan technology (e.g., fMRI, EEG) can only investigate underlying mechanisms with gross-scale measurements. The resolution of non-invasive brain-scanning devices per unit volume is doubling about every twelve months.[11] However, sufficient spatial and temporal resolution for recording capability at the cellular (i.e., neuronal and/or glial) level has not yet been attained. In addition, *in vivo* measurement capability is currently limited by a number of factors, including insufficient resolution, bulky, large and non-subject-friendly machines, and lack of basic subcutaneous brain interface devices.

- **Improve spatial and temporal resolution of neuroimaging and other brain data collection tools.**

  The current capabilities in neuroimaging have developed entirely as a result of clinical needs; X-ray, PET, SPECT, MRI, fMRI, DTI and other technologies (e.g., neurogenomics/genetics, neuroproteomics, etc.) all emerged from the need to depict pathology in the brain. These technologies have developed increasingly fine levels of resolution, but specific limitations in temporal and/or spatial accuracy still constrain highly detailed clinical and/or non-clinical use. While fMRI, PET, and SPECT have been used to examine functional aspects of the brain, they only provide gross-scale images. In order to understand the brain's function, highly detailed, neuron-resolution imaging will be needed.

  Figure 6 demonstrates the rate of increase that has been achieved in the past three decades in spatial resolution of brain imaging and the speed of image reconstruction across all noninvasive modalities. Despite such progress, the desired level of spatial and temporal resolution still lies far beyond current capabilities. The current level of resolution for fMRI, which is the primary modality for functional studies, averages about 2-4 mm, or about 0.5 mm in larger, state-of-the-art scanners. However, fMRI still provides only an indirect image of brain function, as it measures differential paramagnetic signals of oxygenated versus non-oxygenated hemoglobin as a reflection of regional fluxes in cerebral metabolism and activity. The time difference between neuronal and glial activation and the paramagnetic signal may be as variable as 2-10 seconds, which is clearly inadequate for accurate representation of brain activity mapping. PET scans have higher temporal resolution, up to tens of nanoseconds, but have poor spatial resolution. Often the co-registration of multiple modalities is used to de-limit the relative constraints of each, but very few can actually be performed simultaneously. Neurons vary in type and size, but their cell bodies can range in size from 4 to 100 micrometers, and axons vary in length but are generally about one micrometer in diameter. Electrical signals move between neurons on a scale of milliseconds. The human brain is estimated to have about 100 billion neurons and 100 to as many

11. Kurzweil, Ray. "When Humans Transcend Biology." Presentation given September 17, 2005 at Accelerating Change 2005 Conference.

as 1,000 trillion synapses. The types of concurrent noninvasive measurement capabilities that are presently available are simply insufficient to resolve the level of detail necessary to separate the function of individual components of the brain.[12]

Enhanced resolution will provide a much more comprehensive representation of these substrates, from the cellular to meso-level network functioning. The requirement for increased resolution is listed here, foremost, rather than in the following section on technological requirements because the principal merits are not merely better resolution, but instead represent a saltatory leap in using tools-to-theory-to-tools heuristics to more accurately depict and define neuronal and meso-level function through the development and applications of heretofore unavailable technology. Simply put, development of new and more capable neurotechnologies will enable vastly improved assessment, insight and ability to access the intricate workings of the brain.

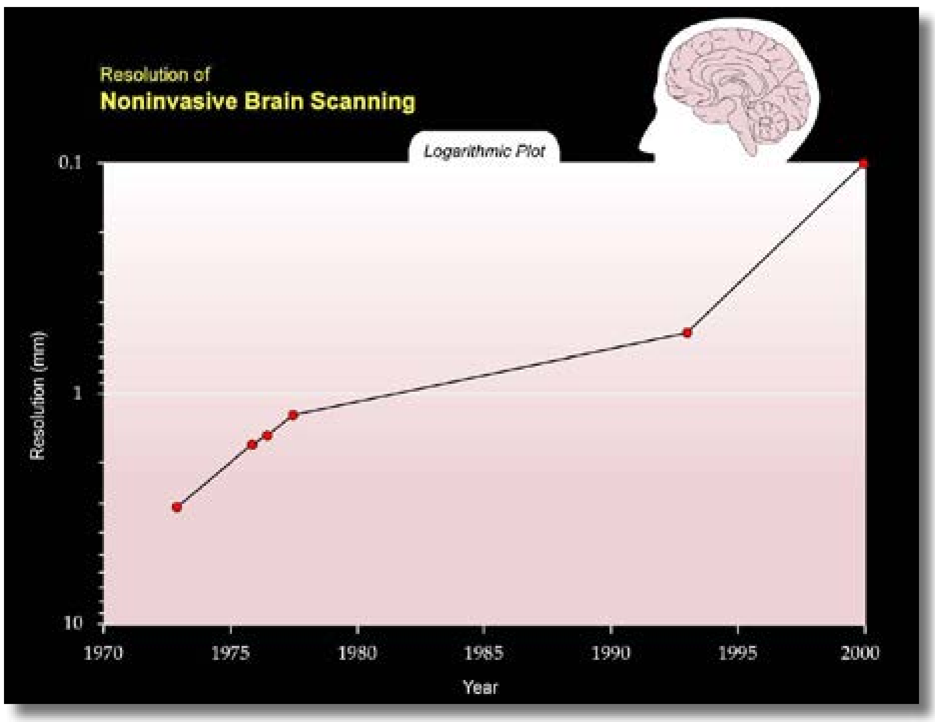

FIGURE 6: GRAPH BY RAY KURZWEIL SHOWING INCREASE IN RESOLUTION OF NONINVASIVE BRAIN SCANNING OVER THE PAST THREE DECADES.[13]

12. VanMeter J. Neuroimaging. In: Giordano J, Gordijn B. (eds) *Scientific and Philosophical Perspectives in Neuroethics.* Cambridge: Cambridge University Press, 2010; p. 230-244.

13. Kurzweil, Ray. "When Humans Transcend Biology." Presentation given September 17, 2005 at Accelerating Change 2005 Conference.

- **Develop altogether new instruments and measurement capabilities.**

  As stated, increased resolution of existing tools would contribute to a major leap in understanding of the brain, but there is also a desire on the part of researchers for entirely new tools and capabilities. These must be more compact, more user-friendly, and more robust for *in vivo* studies, but with suitable resolution. This also implies the potential for field level or wearable applications that would enable research in real-world conditions. It is conceivable that brain activity measurement and processing equipment could feasibly be embedded into garments, headgear, and platforms such that real time measurement could be achieved in military and/or other contexts.

- **Signal processing techniques applied to neuroscience research are drawing new information out of existing data and may lead to new discoveries.**

  While there is currently good work in this area, much remains unknown about the complex electrical signals and fields generated by the brain. New techniques from disciplines such as signal intelligence are being applied with some success. Decoding the signals of the brain and mapping its activities are explicitly on the horizon, but remain a challenge of evolving and perhaps unknown difficulties.

- **Network or co-locate of all state-of-the-art imaging capabilities.**

  Unfortunately, there is is a paucity of single locations (i.e., hospital, university, or industry setting) that house all of the most modern imaging capabilities necessary for the level of investigation and analysis required for detailed brain activity mapping. This lack of availability limits the ability to correlate findings of brain activity across neurobiological domains (e.g., metabolism, anatomy, etc.), and thus retards the advancement of breakthrough science. In addition, data that are unique to a specific collection, patient, experimental design, or sponsor, remain particular to that collection's purpose and often cannot be generalized to provide data to other researchers.

- **Increase analysis of existing data by using signals analysis tools and developing advanced computing tools.**

  Detection and analysis of communications, signals and processes in the brain (also referred to as "decoding the brain") may be achieved through application of signals intelligence processing techniques. This analysis could begin immediately with existing brain data. This will require increased resolution of tools used to measure neural signals, and developing a basic brain interface technology, for seamless, two-way input and output between the brain and external devices (see "Track 2: A. Brain Interface Technology"). There is reason to believe that advanced signal processing technologies, particularly declassified techniques that originated in the very complex domain of signal intelligence, will be useful in extracting a significantly higher yield of signals from a presumably very noisy floor of brain activity. This is possible and probable for the processing of various types of EEG data, and at least possible for other brain recording techniques as well.

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- **Scientific development is being stifled by a lack of data sharing, availability, compatibility, and collection standards.**

  Availability and compatibility of data are a major issue in the field of neuroscience. Due to the clinical focus of most neuroscience research and the high cost and footprint of most imaging and data collection machines, the majority of data collection occurs in hospital or clinical research centers. Most of these large imaging devices are paid for by private contribution or are major investments by the hospital or research center. The NIH funds researchers, but does not generally invest in large-scale infrastructure needs, like machines. Thus, data from these studies are often held as proprietary information by the institutions that own them. As a result, much of the raw data collected are not released or published, so other researchers can neither verify results of studies nor replicate them.

  Researchers tend to be clustered around these centers because they are a necessity for conducting the type and extent of research that affords the most advantageous outcomes. While some efforts are being made to enable greater neurotechnology availability and access for researchers, this remains competitive and those who do not have ready access to multiple types of imaging technologies are thus unable to conduct first line research.

- **Data standardization continues to be imperative.**

  In the market-driven mode of developing medical applications, and in the pursuit of basic research, there have been some meaningful developments in the standards for the collection, analysis, storage, and sharing of brain/behavioral data. Based upon these initial successes, the community should be incentivized to produce additional standards, and these incentives should effectively pre-empt what could otherwise become the types of legal and indemnity-oriented data mandates that have the potential of prescribing standards that are far less than adequate for scientific pursuit and social applications.

- **New and shared computing and analysis tools are needed.**

  As discussed above, today each lab is challenged by engaging the tools it possesses to address specific questions of neuroscience. This can lead to a relative siloing of the use of neurotechnology and the heuristics of neuroscientific theories. In addition, the volume of data collected generally far outpaces the ability to analyze (all of) it. To effect change in these existing constraints, a paradigm of advanced integrative scientific convergence (AISC) has been proposed to de-silo opportunities for exchange and cooperative development of neurotechnology, neuroscientific techniques, ideas and problem solving.[14,15] While technical approaches to sharing these tools and techniques would not be difficult, this new methodology represents something of a sea change in the particular and overall infrastructures of the academic and commercial enterprises that are dedicated to neuroscientific research, and would therefore have to overcome social barriers and proprietary reluctance to share. Our ongoing work has been dedicated to demonstration of how this AISC approach to neuroscience could instantiate major progress in the field.

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14. Vaseashta A. The potential utility of advanced sciences convergence: Analytical methods to depict, assess and forecast trends in neuroscience and neurotechnological developments and uses. In: Giordano J. (ed.) *Neurotechnology: Premises, Potential and Problems*. NY: CRC Press, 2012, p. 15-37.
15. Giordano J. Integrative convergence in neuroscience: trajectories, problems and the need for a progressive neurobioethics. In: Vaseashta A, Braman E, Sussman P. (eds.) *Technological Innovation in Sensing and Detecting Chemical, Biological, Radiological, Nuclear Threats and Ecological Terrorism.* (NATO Science for Peace and Security Series), NY: Springer, 2012.

- **A system for increasing mechanisms and vectors for sharing data and analysis tools that improves on existing capabilities should be inaugurated and supported as a national repository for neuroscience data.**

  This undertaking should build upon existing efforts in this domain by mirroring other well-known and highly successful models such as the national level development and management of astronomic telescopes, wind tunnels, etc. for shared use among qualified – and contributing scientists and engineers. NIH currently supports a system for sharing brain research data called the Neuroscience Information Framework (NIF), which is enjoying some success in making large amounts of brain data available to participating researchers. NIF was designed to serve the biomedical community and offers data, materials, and tools to advance research by enabling discovery and access to public data via an open source, web-based database.[16] Dr. Bruce Rosen of the Martinos Center for Biomedical Imaging, a leading neuroscience research institute in Boston, suggests an "iTunes" model for data-sharing, which would be integrated into researchers' existing tools, would make choosing to share data as simple as clicking a button, and would give researchers an incentive to share their data by offering access to the other shared data in return. Ashok Vaseashta of the U.S. State Department has advocated that use of AISC would further enable data sharing and real-time transfer protocols that would allow multi-disciplinary integration of large-scale data depositories to afford high-level computational analyses of a variety of (types and tiers) of neurotechnologically-obtained information.[17] The NIF should be expanded as an interagency effort to include participation for a variety of scientific communities.

Examples of Potential Projects:

- Establish regional, integrated, multi-disciplinary research centers for data collection and analysis, with advanced imaging, data and signals analysis tools, that will lead the field by sharing tools and data, and establish universal standards for data formatting.
  - Co-locate collection tools for large-scale, multi-modality studies. Network instruments at multiple sites.
  - Make data and analysis tools accessible to the community of researchers; incentivize sharing from other institutions, and set formatting standards for the field.
  - Attract multi-disciplinary teams of researchers to enhance cross-pollination and encourage new discoveries.
  - Ensure that research and data are shared, and access is based on the quality of proposed research (similar to processes used in the astrophysics and high energy physics communities).
- Apply advanced signal processing and intelligence recognition tools and techniques to brain signals' data.
- Develop sensors that can collect brain electromagnetic fields with very wide dynamic range and sensitivity.
- Develop internal sensors and signal injectors that can operate at the 10^3 neuron and fine scale single cellular level.
- Develop and advance multi-scale imaging of the living human brain (from molecular to whole brain levels).

16. Gardner D, et. al. The Neuroscience Information Framework: A data and knowledge environment for neuroscience. *Neuroinform*. 2008; 6(3):149-60. DOI 10.1007/s12021-008-9024-z.
17. Vaseashta A. The potential utility of advanced sciences convergence: Analytical methods to depict, assess and forecast trends in neuroscience and neurotechnological developments and uses. In: Giordano J. (ed.) *Neurotechnology: Premises, Potential and Problems*. NY: CRC Press, 2012, p. 15-37.

Similar efforts in data standardization and data availability are found at the Protein Data Bank (PDB) hosted by the Research Collaboratory for Structural Bioinformatics. The PDB is an information portal to biological macromolecular structures. Major publishers require protein structure data to be submitted to, and analyzed by PDB prior to publication. This enables standardization and auditing of data, as well as making the data publically available.

B. Advanced Computing, Modeling and Simulation

An integral part of improving data collection and analysis lies in the computing and modeling tools available to researchers; major needs of the field include tools for data synthesis, analysis, modeling and simulation. Key research areas will include cognitive computing, multi-scale modeling of the brain, simulation tools, and advanced visualization tools. The future development of new tools to understand and interface the brain will rely on modeling and simulation for research and testing.

- **Modeling and simulation of parts of the brain are needed.**

  There has been a great deal of modeling of certain parts of the brain, but less has been done at the meso-level of brain substructures, subsystems and networks. Significant gains have been made in modeling some subsystems, such as the auditory and visual systems, and neuromorphic models of the cerebellum, especially as related to pattern recognition capabilities. Progress has been made in developing an artificial hippocampus (e.g., rat brain model incorporated on a chip) and olivocerebellar regions (responsible for balance and coordination), as well as serial models of various neural activity networks that are tentatively contributory to an overall map of intra-network connectivities (i.e., the "connectome").

- **Apply advanced computing to improve or create tools for data analysis, modeling and simulation.**

  Researchers currently spend considerable time analyzing data. In large part, this is because the ability to generate massive amounts of data has outstripped the capability of individual researchers to employ computational analytic tools at their disposal. This has constrained the speed and efficiency of neuroscientific research. Better analysis of data will depend on both new collection and analytic tools and also incorporation of wide-scale sharing of such data analysis and tools. Given trends toward standardization of computational methods in data analyses, an important next step will be the development of computing initiatives that are integrated with research centers to enable enhanced collaboration toward sharing of tools and techniques.

- **Constructing multi-scale views of the brain (from neuron to whole brain level, from multiple temporal and spatial perspectives) will allow scientists to portray otherwise overwhelmingly complex relationships among networks, meso-structures, associated large scale system-wide behavior, etc.**

  The simultaneous representation of more than four variables, with the implied dual and multi-way interactions among variables, approaches or exceeds the limits of human visual-cognitive capability. Thus, the provision of easily prosecuted, model-based representation of otherwise excessively complex phenomena will lessen – if not rectify – scientists' perdurable problems in the acquisition, transformation and analyses of neuroscientifc data. This will require advanced (and shared) processing and imaging tools, increased computational power, three-dimensional (3-D) and large-scale, multi-format displays, coupled with theoretically competitive, integrated models of the brain and cognition.

Examples of Potential Projects:

- Develop integrated models of the human brain and cognition: Generate an approximation that can be used as a basis for explanation, simulation, and experimentation at macro and micro levels (e.g., similar to global climate modeling). Use these constructs to incorporate models and theories of cognition and mind from other disciplines (e.g.., psychology, AI, etc).
- Computationally integrate existing brain imaging techniques to enhance spatio-temporal resolution and increase fidelity of activity mapping.
- Develop brain-computer interface languages (in cooperation with clinical researchers).
- Advance visualization and analysis tools to build on existing Federal government information technology (IT) and computing strength and leverage petabytes of existing brain data.
- Expand existing computational neuroscience programs and develop new capabilities based upon increased neurotechnological output.

C. Greater Understanding of Neural Structures and Functions

The field of neuroscience is growing, and while its body of knowledge is immense, there is much that is still unknown about the brain and cognition. While a complete understanding of the brain may be an ultimate goal, we recognize that this is optimistic, at best. However, there are several areas of research that hold great promise for the achievement of more proximate and realistic goals, which are directly possible through the continued advancement of neurotechnology. Deeper basic scientific knowledge in these areas could have major implications for the advancement of neurotechnology applications in medicine, public life and national security. Primary needs are to understand the connection between brain structure and functional cognition, and to understand neurodevelopment, neurogenesis, plasticity, learning, and memory. There are also major gaps in the understanding of neural connections, and the form and pattern of communications at many levels in the brain, from molecular to the inter-cellular (i.e., neuronal and glial) to the meso-level (between and among nuclei of the brain) and macro-level (between brain and body and between organisms and environments).

- **Further research on brain function and architecture is needed.**

  While great strides have been made in understanding micro-level phenomena (cellular level), and in relating cognition and behavior to brain function, little is understood about the systems' meso-level structure and function of the brain. Some advances have been made in understanding higher-level functions, including imitation, prediction and emotion, but their relation to measurable processes in the brain remains only vaguely understood.

  The Human Connectome Project funded by NIH strives to provide a compilation of neural data with an interface to navigate the network connections and properties of the brain. This is the beginning of a large-scale informatics research infrastructure to collect and share data at the scope and detail sufficient to address fundamental questions about brain anatomy, variation and activity. Incorporation of genomic, genotypic and phenotypic data in this database allows researchers to correlate patterns of brain network activity with individual cognitions and behaviors.

- **Understanding neural structures and functions depends on improved data collection and analysis capabilities.**

  Although some capability for single cell recording currently exists, high fidelity large-scale (i.e., multiple cellular array) measurement is not fully developed. Nor is the capability to measure the real time effects of stimulation of brain tissue or cells in clinically applicable models. Tools for *in vivo* observation, interaction and manipulation from the cell level to the large-scale, with spatial and temporal resolution sensitivities down to the cellular level, while currently in early development, show great promise, and will provide the necessary technologies and techniques for the theoretically-driven research objectives that offer high translational viability and clinical value. (See also "Track 1: A. Precision Measurement and Data Collection," and "Track 2: Brain Interface Technology"). Within the last decade, progress has been made in *in vivo* measurement techniques, aided largely by DBS and intra-cranial magnetic stimulation and recording (ICMS/R) technologies. This is an important step because it upholds the interactions between tools and technologies that directly correlate to advancement and progress. In addition, ongoing developement of such higher-resolution tools and techniques may help unravel the connections and communication between different elements and levels of the brain.

- **Neurodevelopment and neurogenesis are not yet fully understood, but may hold the key to future progress in central nervous system (CNS) repair.**

  Arguably the most complex of biological phenomena, neural growth unfolds developmentally as a function of both a prescribed anatomical architecture, and of the endocrinological and behavioral consequences of (internal and external) environmental experience. In fact, neurological development follows a general pattern of "nature via nurture" in which the proliferation and pruning of neural cells in the central nervous system proceeds in a non-linear way based upon input(s) from the internal and external elements of the embodied organism that is embedded in its environment.[18] Brain growth occurs beyond what is considered modern adulthood. There now appears to be a significantly systematic change in the concentrations and ratios of white and grey matter of the brain into human adulthood, perhaps to as late as the sixth decade of life. Unlocking nature's strategy for cell differentiation and growth is extremely important because (1) neuronal networks help stimulate and regulate the functioning of other organ systems, and (2) neuronal networks are the basis of the most important requirement of life – behavioral interaction with the outside world. It was long believed that post-natal neurogenesis did not occur in adult mammals; recent research, however, has shown that neural cells in certain brain areas do, in fact, regenerate. Far more research in this area is needed to understand this process and the mechanisms by which it occurs, with the goal of someday harnessing the power of neurogenesis to repair damage and restore function in the CNS, which may be of value in clinical interventions against a variety of neurodegenerative disorders and traumatic insults[19] (see "Track 2: B. Brain Injury Detection, Prevention and Repair").

18. Wurzman R, Giordano J. Differential susceptibility to plasticity: A 'missing link' between gene-culture co-evolution and neuropsychiatric spectrum disorders? *BMC Medicine*. 2012; 10:37.
19. Giordano J. A big picture: Neurogenesis, pain, the reality of neurotechnology and the ethics of pain medicine. *Prac. Pain Management*. 2007; 7(2):37-52.

- **Greater understanding of learning, memory and plasticity are key.**

The brain's plasticity holds great potential for future applications in learning, memory, development, and the treatment of disease and dysfunction, but there is still much to be learned. Plasticity occurs in at least two ways; the first is construed at the single cell level. Here, a neuron's algorithm (a complex summative resolution of spatial and temporal inputs) for relaying/generating signals (or not sending a signal), probably changes as a function of the initial conditions specified by its (DNA-driven) integration algorithm, and as a function of the consequences of activity (feedback) as assessed by the organism at the outward behavioral level. The second form of plasticity is a multiple-neuron level phenomenon. Here, neurons affiliate and synapse upon other neurons as the result of development, learning and maturation. Distilling the natural strategy for when and how both varieties of plasticity work suggests the provocative possibility of technology that could "down-load" experience and facilitate learning in a time-compressed manner.

Human capability for plasticity at the behavioral level (known formally as learning or information acquisition) and its preservation (memory) are most remarkable, especially compared to that of a number of other species. The graph in Figure 7 below shows a typical learning curve with the relationship $y' = f(m[1 - e^{-kt}])$. That is, performance (e.g., for the acquisition of a psychomotor skill or behavior, like throwing a ball or marksmanship) on a next trial is statistically a function of *'t'* (quantity of practice), and *'k'* (a genetic endowment, as is *'m'*).

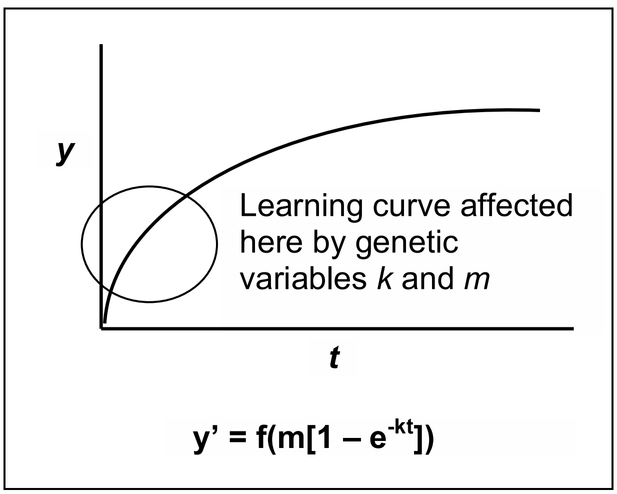

FIGURE 7: GRAPH OF EFFECT OF GENETIC VARIABLES ON STANDARD LEARNING CURVE.

The curve shows that individuals improve with practice (the variable *'t'* indicates quantity of training or time). But the variables *'m'* and *'k'* appear to be largely associated with genetic variation.[20] As the mathematics of the equation suggests, hereditary components equal, or actually exceed the contributions

20. Noble CE. Age, race, and sex in the learning and performance of psychomotor skills. In: Osborne RT, Noble CE, Weyl N (eds.) *Human Variation*. NY: Academic Press, 1978.

provided by practice alone. Thus, better understanding of learning and memory at the neuronal- and meso-levels will enable enterprises such as the educational system and/or the military to significantly improve teaching techniques for iteratively more complex knowledge, skill sets (ranging from basic science, technology, engineering, mathematics [i.e., STEM] and the social sciences and humanities, to nighttime carrier landings) and decision-making under stress. But the gains that can be achieved from better teaching strategies will pale in comparison to the improvements that will be derived from better selection and assignment strategies. Knowing an individual's *'k'* or *'m'* "score," for example, would optimize his or her assignment in terms of acquiring the skills necessary for a particular career field. Unfortunately, the Services more or less cancelled their respective programs in so-called "selection research" during the 1990s. Neurotechnology could enable research that will make the Defense Department the world's leading pioneer and user of very advanced selection technology (as it did for fifty years at the molar behavior level of investigation and theory).[21]

As well, greater understanding of the neural mechanisms of learning and memory are needed to provide the appropriate theoretical basis for neurotechnologically enhancing learning, or for selectively preserving or muting memory. This would be especially helpful in treating cases of post traumatic stress disorder (PTSD), which epidemiologically is at an all-time high, and which poses a significant challenge to military medicine.

- **Understand the connection between structure and cognition.**

  In recent years, neuroimaging approaches (such as fMRI) have contributed to major advances in understanding connections between structural activity of the brain and cognitive function. However, too little is known about the relationships of various meso-structures in the brain and functional aspects of cognition. Part of the deficit is the product of little cross-fertilization among specialized groups within the relative academic silos of neuroscientific research. While a convergent multi-disciplinary approach to the unified model and complex systems architecture of the brain argued for in Track 1 will help address this issue,[22] there are implications for this issue that bear not only on the theoretical, but on practical technological issues as well (e.g., capacity to image and record from multiple brain structures and define function(s) in cognition, emotion and/or behavior).

Examples of Potential Projects:

- Initiation and support for projects designed to understand relationships between brain structures and function at the micro-, meso-, and macro-levels of the brain.
- Expanding research in neurogenesis, plasticity, learning, memory, and their neural correlates. Identifying measurable signatures of cognitive functions including emotion, skills acquisition, learning, etc. with high resolution.

21. (a) Kalbfleisch ML. Is the use of neurotechnology in education an enablement, treatment or enhancement? In: Giordano J. (ed.) *Neurotechnology: Premises, Potential and Problems*. NY: CRC Press, 2012, p. 37-46. (b) Stanney K, Hale K, Fuchs S, Baskin A, Berka C. Training: Neural systems and intelligence application. *Synesis: A Journal of Science, Technology, Ethics and Policy*. 2011; 2:121-128.
22. Giordano J. Integrative convergence in neuroscience: Trajectories, problems and the need for a progressive neurobioethics. In: Vaseashta A, Braman E, Sussman P. (eds.) *Technological Innovation in Sensing and Detecting Chemical, Biological, Radiological, Nuclear Threats and Ecological Terrorism.* (NATO Science for Peace and Security Series), NY: Springer, 2012.

- Identifying and determining operational ways in which brain centers communicate and interact to create the neural bases of cognition, meaning and actions.
- Mapping functions to structure in sufficient detail to support realistic simulation.

D. Theory of Brain and Cognition, Complex Systems Architectures

The ultimate goal of "Track 1: Fundamental Science" is to develop a multi-scale, integrated, verifiable, theory-based model of the brain. Such a model would build on all elements of this track, from greater understanding of neural structures and functions to modeling and simulation tools. This complex system modeling would merge macro models comprised of a large number of smaller models of underlying systems, and move toward a more integrated model of the brain and cognition that would allow simulations and testing of hypotheses; these constant revisions would significantly advance an overall – as well as specific – understanding of the brain and cognition.

- **A multi-scale, integrated, theory-based model of the brain and cognition is needed.**

  An integrated, theory-based model of the whole brain and cognition is needed to bring together a large number of smaller conceptualizations or construct sets of underlying systems into a macro-level, complex systems model of brain activity. A similar example can be seen in global climate models, which integrate multiple levels of complex systems to understand a more unified systems' approach to weather, climate variation and short-, intermediate- and long-term climatic shifts.

- **Develop complex systems architecture of the brain.**

  It appears that efforts to represent mammalian central nervous system architectures are dominated by an anatomical orientation. This anatomical orientation is consistent with biological systematics (i.e., classification or taxonomy research). Much of neuroscience is focused on anatomical relationships; we believe that this is limiting breakthrough neuroarchitectural-level research that could contribute a viable architecture of the nervous system that is crucial to understanding network and whole-brain activities. An alternative approach would be to pursue nervous systems as complex adaptively dynamic systems. Rather than a more reductionist focus on, for example, neural "connections", perhaps an equally or more productive strategy would be to pursue neuro-architecture via more ecologically-oriented phenomenology. There have been attempts to achieve this, which, while generating some controversy, (for example Gerald Edelman's *Neural Darwinism: The Theory of Neuronal Group Selection* (1987)), are now being more widely accepted into a paradigmatic approach to neuroscience. The pushback against a complex adaptive systems approach may be partially attributed to the venerable mission boundaries of neuroscience journals and academic imperatives to publish within a narrowly defined field, neither of which encourage broader-view integrative research. Only recently have efforts been made to bring these fields together in an interdisciplinary approach to solving complex systems problems.

  An important attempt at such a project is the Allen Brain Atlas at the Allen Institute for Brain Science, a privately funded data portal for public use. The Atlas includes gene expression maps, maps of neural connections in the mouse brain, and a map of a developing human brain. It is a collection of resources, gene expression and neuroanatomical data, and search and viewing tools. This, along with the Human

Connectome Project, previously described, are individual attempts to gather enough data to understand the complex architecture of the brain. A nation-wide effort is necessary to ensure such goals are met by combining all of these individual research programs into a larger and more unified effort.

- **Develop an integrated theory of brain and cognition, analogous to global climate modeling.**

  Many branches of science, from neurophysiology to behavioral psychology, have developed theories of cognition. However, no singularly integrated model of the brain, cognition, and behavior currently exists that could be agreed upon or used predictively across disciplines.

  To re-iterate, a good analogy for this type of approach is global climate modeling. In climatology, understanding and predictive capability exist at several different levels of analysis, from small-scale physics and chemistry of hydrology to the large-scale dynamics of global weather systems. While small-scale factors in the model are well-understood and predictable, the overall, long-term predictive capability of the models are less certain, as varying estimates of future trends in global warming attest. Even day-to-day local weather prediction has limited accuracy. However, these models are extremely useful in providing guides for understanding and prediction, though they may be approximate.

  Neuroscience and neurotechnology currently lack such systems-type approximate models to explain the brain and cognition in an integrated fashion. While there is a move toward more systems'-oriented neuroscientific research, and a generally good understanding of individual processes at the small-scale, and behavior at the large-scale, there is no neuroscientific equivalent of the "global climate model" to relate these multi-scale views or to provide any testable predictive capability. Such a theory may be largely inaccurate at first, but will aid in generating approximate models that can then be tested to advance overall understanding of the brain and further develop the model. This process will depend heavily on computing capabilities and the integration of data from multiple disciplines (i.e., integrative convergence), such as advanced modeling tools and simulation, on advancing understanding of the structures and functions of the brain, and the complex systems architecture that ties all these processes together (the Track 1 elements A, B, and C above). In turn, as it evolves, it will illuminate these areas through prediction, testing, and simulation.

Examples of Potential Projects:

- Development of a macro-model of the brain composed of several models of brain function (stems from modeling and simulation), similar to global climate models.
- Provision of expanding opportunities for interdisciplinary synthesis of theories of brain and cognition.
- Exploring new and innovative complex systems architectures.
- Developing programs that attempt to simulate experience, emotion, consciousness, etc.

Track 2: Technology and Applications

Based on the advances in an understanding of brain function that derive from the foregoing "Track 1: Fundamental Science," the opportunities to develop prophylactic, restorative, and augmenting technology are staggering. Some of the most promising applications include super-accelerated learning and decision-making, the early detection and mitigation or reversal of neurodegenerative disease, and assistive devices for disabled patients. Further, in the future we envision devices that provide direct communication between a brain and computer(s), between two or more brains (and their augmenting devices), and/or advanced computing that converges on the capabilities of the human brain. Some of the potential neurotechnology applications may even provide deeper insight to what it truly means to be human.

There are four major areas outlined below that will be stepping stones toward achieving the promise of neurotechnology:

A. **Brain Interface Technology;**

B. **Brain Injury Detection, Prevention and Repair;**

C. **Cognitive, and Behavioral Augmentation; and**

D. **Cognitive Computing and Synthetic Brains.**

The primary stepping stone is the development of brain interface technology, which is likely to emerge via clinical applications already in use today. Technologies to detect, prevent, and repair brain injury will also emerge from the clinical realm. Both of these areas will be instrumental to further efforts to complement or augment human capabilities. Cognitive computing and synthetic brains will rely on progress in the modeling and simulation and integrated models of neural networks and whole brain and cognition systems as outlined above, and will lead to the convergence of human-machine interaction with highly advanced machines based on human patterns of cognition.

A. Brain Interface Technology

Two-way, input/output technologically-enabled direct communication with the brain is an ultimate goal for both research and clinical use and will be key to future applications. There have recently been major gains in such technology, but there is still a long way to go to reach a seamless, functional, two-way interface between the nervous system and a computer, chip, or some other device. Key needs to achieve these ends are outlined below.

- **Brain interface technology will be key to future applications.**

  Much of the research on brain interface technology is focused on clinical applications, with neural prosthetics primarily under development for use in patients with paralysis, stroke, movement disorders (e.g., Parkinson's disease, multiple sclerosis), and other disease or injury of the central nervous system. Research on brain signals and output is largely focused on clinical applications as well, such as understanding motor signals or using EEG and fMRI to understand cognitive function.

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Progress is being made in the ability to interface directly with the brain for input and output of signals. While significant advancements have been made in the reduction of implant scale and increased fidelity of stimulating and recording probes, the current technology can still be viewed as rudimentary. However, as this capability increases, its potential applications will expand exponentially, and many of the technologies being developed for clinical use could be adapted to augment cognitive and/or behavioral functions in the near future. Recent developments in brain implant and interface technologies have allowed much finer resolution of inputs and output. Yet, further investigation of these technologies and techniques will be necessary in order to create fine-scale activation of defined populations of neural networks that are involved in specific cognitions and activities.

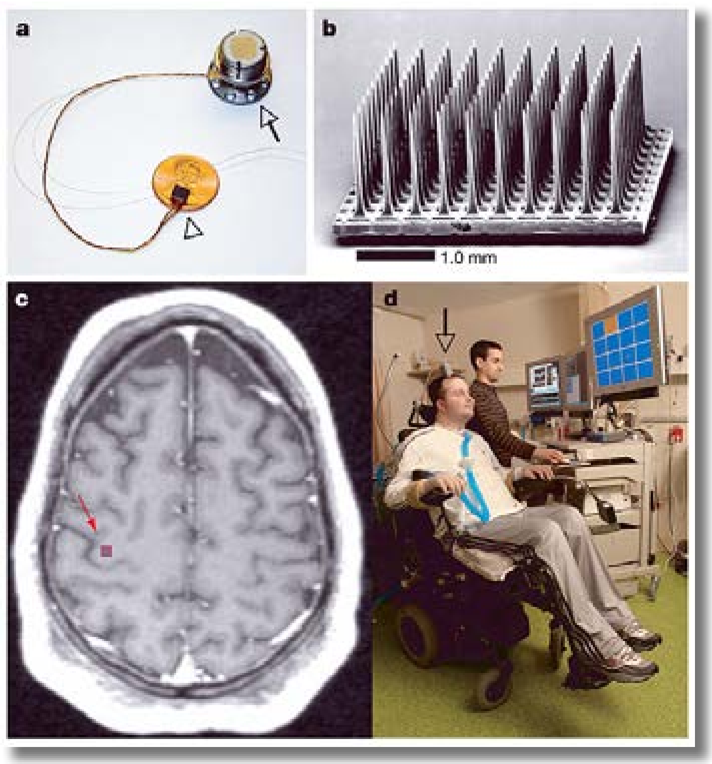

Figure 8: BrainGate device, presented by Dr. Leigh Hochberg at Neurotechnology Futures Workshop, Boston, May 24, 2006. Tetraplegic patient Matthew Nagle moves a computer cursor and mechanical arm via the BrainGate device, which processes neural signals and translates them into movement commands.[23]

23. See: Hochberg LR. et al. Neuronal ensemble control of prosthetic devices by a human with tetraplegia. *Nature.* 2006; 442. http://www.nature.com/nature/journal/v442/n7099/full/nature04970.html.

- **Continued development of emerging brain interface technologies with the ultimate goal of a simple, implantable, low-risk, long-lifespan input and output interface.**

  As evidenced during conferences sponsored by the NIH,[24] direct implantation of micro-sized devices in the brain is already being achieved. In the medical arena, devices like Cyberkinetics' NeuroPort and BrainGate[25] systems (see Figure 8 above), and devices used for deep brain stimulation (DBS), and intracortical electrical and magnetic stimulation (ICMS) have made major progress in directly interfacing the brain, but still rely on gross-level input and output of signals. These technologies represent very important scientific and clinical progress, and are major steps toward enabling future neurotechnology applications; however, many science and engineering hurdles remain. The emergence of a high-resolution input/output device will be fueled in part by advances in "Track 1: Fundamental Science, A. Precision Measurement and Data Collection," and in turn will lead to advances in all areas of "Track 2: Technology and Applications."

- **Improve signal processing and resolution (to the single-neuron level) of brain interface devices.**

  Using recently developed technology, signals can be recorded, and can be injected, at precisely targeted brain locations. However, requirements for neurotechnology remain very steep in terms of the tradeoffs between (1) precise localization of neural signals and information processing in the brain, and (2) the computational processing of a vast field of signals that are embedded in noise. To provide some perspective, a cubic millimeter of brain tissue contains approximately 100,000 neurons operating at 10 to 1,000 signals per second, translating to a total spike output of one million to one billion (resting or active states) per second per cubic millimeter. The sheer burden of processing these data is daunting. Of course, invasive implants will ordinarily focus on volumes much smaller than cubic millimeters; but the trade of precision versus volume, and signal versus noise, is one that neurotechnology computing must address. This element is directly related to "Track 1: Fundamental Science, A. Precision Measurement and Data Collection," as increased capabilities for neurotechnologic devices will develop in conjunction with new data collection tools.

- **Use brain interface devices to record, decode and understand brain signals and their relationship at a functional/structural level to how information is transmitted to the brain and stored.**

  This will be an integral part of "Track 1: C. Greater Understanding of Neural Structures and Functions." Greater understanding of the brain signals involved in cognition, learning, memory, acquiring skills, emotion, and decision-making will help lead to training and other applications that inform augmentation efforts in the future.

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24. Neural Interfaces Workshop, held August 21-23, 2006 in Bethesda, Maryland. Neural Interface Conference held June 18-20, 2012 Salt Lake City, Utah. Sponsored by NIH, National Institute of Neurological Disorders and Stroke (NINDS), National Institute of Mental Health (NIMH), National Institute on Aging (NIA), National Institute of Biomedical Imaging and Bioengineering (NIBIB), and National Institute on Deafness and Other Communication Disorders (NIDCD). http://conferences.masimax.com/neuralinterfaces2006/.

25. BrainGate: Turning thought into action. braingate2.org.

- **Further development of brain interface technologies for prosthetics and restoration of function after injury or disease.**

  There is optimism that spinal injury, paralysis, as well as other neuro-motor (e.g., "locked in" syndrome), and perhaps certain forms of neuro-cognitive conditions can be overcome to some degree by effectively "leaping over" and/or re-integrating damaged or dysfunctional neural network circuitry.[26] There has been recent progress, partially due to DARPA's program Revolutionizing Prosthetics, among other projects, in neurally-controlled prosthetics; (primarily, but not necessarily implanted) devices that detect cerebral activity to control normally voluntary limb movement can control prosthetic actuation devices. It is quite conceivable that with appropriately accelerated training, more precision and a better coupling of the brain's intentional activity to more specific and articulate output will be enabled by high-yield neuroprosthetics in the near future.[27] Improved prosthetics will also rely on advanced robotics and engineering; see the next section, "Track 2: B. Brain Injury Detection, Prevention and Repair," for further detail.

- **Transition of clinical devices for possible augmentation applications.**

  Any potential neurotechnology-based augmentation capabilities will depend on development of sophisticated brain interface technology. To re-iterate, there is still a considerable amount that remains to be known about the structure and functioning of the brain, and we do not have the types of sufficiently sophisticated devices to enable direct access and acquisition of cognitions; major gains must be made in these areas before we can attempt augmentation through direct interaction with the brain. DARPA will play a key role in exploring these possibilities and transitioning clinical devices to such potential applications.

Examples of Potential Projects:

- Enabling control of advanced prosthetic devices by neural interface (via neural signals).
- Investigating technologies and techniques for signal introduction into the brain;
- Fully decoding signals from the brain and associating these with cognition and/or behavior.
- Developing neuron-level interfaces of higher resolution and scope.
- Developing nanotechnology devices for brain interfacing.
- Recording, decoding and understanding brain signals via input/output interface devices for applications such as collection of experiences, training, etc.

B. Brain Injury Detection, Prevention and Repair

The ultimate goal of much of neurotechnologic research and applications is the ability to identify, prevent and treat brain injury or disease, and restore or even improve brain function after insult or trauma. Much of the capital of the neurotechnology industry, estimated at over $155 billion, is focused on these applications, from neural devices to neuropharmaceutical treatments for neurological disease. A range of medical neurotechnologies that are dedicated to the treatment and repair of the brain will enter main-

26. Hinterberger T. Possibilities, limits and implications of brain-computer interfacing technologies. In: Giordano J, Gordijn B. (eds.) *Scientific and Philosophical Perspectives in Neuroethics*. Cambridge: Cambridge University Press, 2010, p. 271-282.
27. Chhatbar PY, Saha S. Neuroprostheses: Implications of the current and future state of the science and technology. In: Giordano J. (ed.) *Neurotechnology: Premises, Potential and Problems*. NY: CRC Press; 2012, p. 93-106.

stream use in the relatively near term. Clinical promise in this area depends on improving basic understanding of the brain and further development of neuroengineering capabilities.

- **Repair of brain injury will one day be achieved.**

  Repair of brain injury appears possible in the future given the extension of work being done today in the field. Advances in brain interface technologies, research into neurogenesis and regeneration, and greater understanding of the brain's plasticity and ability to compensate for lost functionality, all point to improved capabilities for restoring lost function through the regeneration and/or technical compensation of damaged or destroyed neural tissue.[28] Brain and central nervous system repair is a major area of research in contemporary medicine.

- **Identify and understand early hallmarks and development of neurological disease and injury.**

  Neural tissue may degrade under two major circumstances, and the decay may proceed through two time course profiles. First, degradation can be caused by autodegenerative pathology such as in the neuromuscular disorders (i.e., Parkinson's disease and multiple sclerosis) or age-associated disease (e.g., Alzheimer's dementia). The effects of imperfect cell replication can also be recognized at the organ-performance level (as in simple aging). Tissue can lose integrity as the result of physical or chemical insult from external sources, such as in explosive blasts as exposure to toxins. Second, the time course of cell/tissue degradation can be either necrotic, which begins when the insult occurs, or apoptotic, which is a delayed, cascading cell death process (such as in some cases of hearing loss due to noise overexposure). Neurotechnology holds promise for mitigating all four modes and time course categories, but greater understanding of disease and injury processes, and research into how to slow or prevent these processes, is crucial and is tied to "Track 1: C. Greater Understanding of Neural Structures and Functions."

- **Develop mechanisms for mitigating or preventing neurodegeneration.**

  Neurotechnology has the potential to enable early detection and treatment of neurodegenerative disease. With implanted sensors that can locally assay signs of impending disease, critical information could be sent, for example, as transdermal email messages to a patient and to his/her "network" of care providers. Likewise, finely dosed electrical, magnetic, pharmaceutical or genetic interventions, tailored to each individual, may be administered in order to prevent, forestall, or mitigate the effects of neural degeneration.

- **Early identification of mental or cognitive disorders with neuroimaging and other neurotechnology tools.**

  Brain activity network characteristics that are associated with brain dysfunction, but that are not the result of organic tissue damage may also be detected and conveyed. It is conceivable that with an appropriate brain implant, or perhaps non-invasive input, brain networking may be altered clinically in order to restore proper function. The historical use of electroconvulsive shock therapy, which more or less blindly applied large-field electrical energy to the brain, was an early attempt to alter brain function

28. (a) Giordano J. Neuroethical issues in neurogenetics and neurotransplantation technology – the need for pragmatism and preparedness in practice and policy. *Studies Ethics, Law Technol.* 2011; 5(1). (b) Boer GJ. Transplantation and xenotransplantation. In: Giordano J, Gordijn B. (eds.) *Scientific and Philosophical Perspectives in Neuroethics*. Cambridge: Cambridge University Press, 2010, p. 190-216.

using electrical stimulation. Deep brain stimulation techniques that are used successfully today employ more refined electrical impulses to treat significant neurocognitive diseases like Parkinson's disease, epilepsy, severe depression, certain forms of impulse control disorders, and types of chronic intractable pain. As brain interface technologies are more finely developed and we understand more about the structural and functional aspects of neurocognitive disorders, these intervention methods could be expanded to other areas, including treatments for PTSD, schizophrenia, congenital cognitive and psychiatric disorders, cognitive decline, and the enablement of cognitive and motoric capabilities. This will be somewhat dependent on progress in "Track 1: C. Greater Understanding of Neural Structures and Functions," and "Track 2: A. Brain Interface Technologies."

- **Potential treatment options may emerge as we gain understanding of structural/functional aspects of other neurological processes, such as generation of perceptions of pain, substance cravings, and/or debilitating depression and anxiety.**

  A possible extension of brain interface technologies that modulate brain function could include treatment of more nebulous and complex disorders, such as chronic pain, addiction, and mental illness, but there is still much that is unknown about the neurocognitive bases of these disorders. Novel neurotechnologies have shown great promise in both identifying the neurological mechanisms of these disorders, as well as possible use in – and as – therapeutic interventions.

- **Brain function could someday be restored or replaced after brain injury or disease.**

  Neurotechnology is being developed to restore and/or replace lost functionality by "training" healthy, available brain networks to compensate for neural tissue that has been damaged or destroyed by insult or disease. Recent studies have shown that neurotechnological approaches actually recruit new "networks" to be formed and engaged, rather than activating isolated tissue sections. In some cases, the networks are large and global, in others quite local; however, the overall effect seems to be that the "whole takes over for the damaged parts". This is crucial, because as we gain insight to these compensating network properties through projects such as the Brain Activity Map, we could develop whole new directions for neurotechnological interventions that are "network propagators". Thus, there is considerable potential for exploitation of the brain's plasticity and potential neurogenesis, through stimulation of brain networks, together with the development and use of novel neuropharmaceuticals, to provide positive, clinically important effects. Neurotechnology will enable this enterprise, but significant breakthroughs will be needed in structural and functional understanding, precision targeting and dosage, to control and appropriately connect such newly induced growth of brain tissue and networks.

- **Neurogenesis has great potential to transform neuroscience and medicine.**

  Until recently, it was accepted dogma that central nervous system nerve tissue stopped growing in adulthood and could not regenerate. Scientists including Dr. Fred Gage at the Salk Institute in La Jolla, California[29], have made major breakthroughs in neurogenesis research over the last decade (e.g., images of the growth of new brain cells is shown in Figure 9). Such studies have demonstrated that certain sites within adult brains in fact produce new neurons that are functionally integrated into the brain as a result of cognition, memory, and learning.

29. Salk Institute Press Release. "Salk Scientists Demonstrate For The First Time That Newly Born Brain Cells Are Functional In The Adult Brain." February 27, 2002. http://www.salk.edu/news/releases/details.php?id=10.

- **Goals include stimulating growth of functional, appropriately connected brain tissue after injury or disease, restoring or replacing damaged tissue, and controlling neurogenesis.**

  With recent progress in understanding adult neurogenesis and neural stem cells, there is great potential for adapting or inducing natural processes to aid in brain repair. It is reasonable that neurotechnology, especially coupled with advanced nanotechnology, could stimulate the delivery or generation of neuronal stem cells to physically and functionally replace damaged tissue. Precision is the key to success – neurotechnological breakthroughs will provide accurate cell location for intervention, very localized and specific dosimetric control, and monitoring of progress at the appropriate level of detail (cell to nuclei), etc.

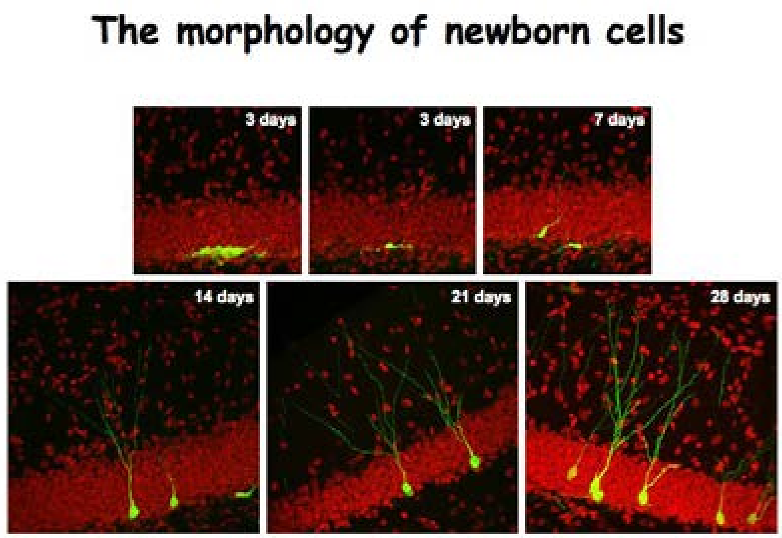

FIGURE 9: IMAGES OF NEW BRAIN CELLS DEVELOPING IN AN ADULT BRAIN. RESEARCH PRESENTED BY DR. FRED GAGE AT THE NEUROTECHNOLOGY FUTURES WORKSHOP IN SAN DIEGO, CA.[30]

30. From Presentation by Fred Gage, PhD, "Neurotechnology: Interface between Neuroscience, Molecular and Cellular Biology, Engineering and Computer Science." Neurotechnology Futures Workshop, San Diego, CA, June 19, 2006.

Examples of Potential Projects:

- Growing functional, connected brain tissue *in vitro* and *in vivo*.
- Developing an approved treatment ("short circuit") for previously refractory neurological conditions such as neurodegenerative disorders, and neuropsychiatric conditions such as severe depression, chronic intractable pain, substance abuse, PTSD, and schizophrenia.
- Introducing advanced prostheses that restore functionality, but also increases (along some dimension) the capability of the recipient beyond what they could achieve prior to injury.

C. Augmented Cognition

The first steps toward augmenting human cognitive capabilities via neurotechnology will not necessarily be in the traditional "science fiction-inspired" framework. Instead, they may include non-invasive devices that complement or supplement human capabilities, such as tools for learning and training augmentation, improved user interfaces based on neurocognitive principles, feedback mechanisms that can give a user immediate information on the state of their performance, and advanced assistive devices for the disabled. Use of physically-connected devices for augmentation may lie farther ahead, and will depend on advances in brain interfaces and greater understanding of brain function and signaling.

- **Neurotechnology applications for learning, memory and cognition.**

  Behavioral science has settled on the proposition that learning is simply the result of active behavioral (i.e., not passive) experience with feedback. The speed and generalizability of learning is thus dependent on the quantity of experience and quality of feedback that can be produced over time. Serious, but largely failed efforts aimed at enhancing learning have included so-called sleep-learning forays, state-dependent learning techniques, and others which show promise, such as game-based methods. The quantity of training that an individual can absorb in a given period of time is limited by real world constraints. It is also known that learning takes place neurologically during post-performance rest. That is, engagement in a training exercise provides the context, pattern recognition and decision-making opportunities, and perceptual-motor practice. During training episodes, feedback is presented to the performer, and science has clearly shown that the most effective feedback is very quick and clearly associated with the behavior being rewarded. But it is in the ensuing rest that the requisite neuronal memory trace-consolidation occurs. Most concentrated efforts on improving learning technology have been focused on the performance component and not on the subsequent trace consolidation component. It appears that technology based on the theoretical breakthroughs afforded by neurotechnology outlined above will enable whole scale changes in both aspects of learning.

- **Neurotechnology applications for augmentation of learning and decision-making.**

  It is understood that a trained individual knows what to do when surprised – but that a learned individual does not get surprised. Thus, true learning is less about acquiring rote relationships between the need to execute behavior X when encountering situation Y, than it is about recognizing that pattern A is changing to pattern B. That is, it is the generalizable principle and not the specific reaction that is the point of learning. This ability comes about through experience and its acquisition is facilitated of course by individual talent, much of which can be measured by intelligence and personality instruments. Based on knowledge of an individual's learning styles and propensities, neurotechnologic applications could rapidly generate scenarios and representations that are presented straight-forwardly to a student's conscious faculties, and that are also inputted directly to underlying – i.e., not consciously involved – brain function in a way that could clearly enhance the acquisition, storage, and retrieval of the learned material.[31]

- **Complementing human capabilities through feedback mechanisms in learning, memory, decision-making, and other cognitive functions.**

  Another reliable finding from learning theory science is that emotion plays a significant role both during the learning process, and during the real situation execution of learned skill. This relationship is best exemplified by the Yerkes-Dodson inverted U-curve (see Figure 10 below), which suggests that arousal level affects performance, and that there is an optimal arousal level for maximizing performance. Moreover, each individual's arousal-performance curve is different (as seen in the graph below, where A, B, and C represent different individuals), and the parameters of the curve change as a function of the individual's experience over time. This implies that a closed loop system, that could be accessed and affected by neurotechnologies to augment the detection and modulation of orientation and arousal in real time, and which could effectively augment learning, could positively affect real world decision-making.

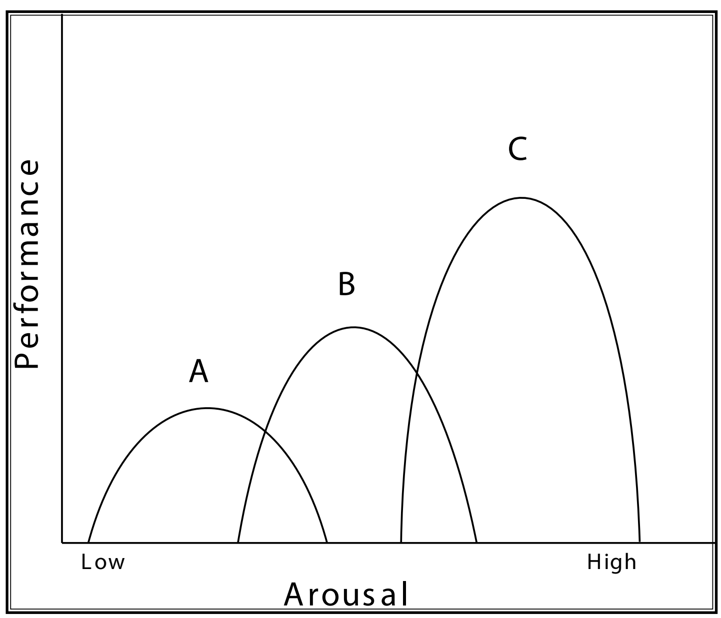

FIGURE 10: GRAPH OF YERKES-DODSON LEARNING CURVE; OPTIMAL CURVES VARY BY INDIVIDUAL.

31. Murray S, Yanagi MA. Transitioning brain research from the laboratory to the field. *Synesis: A Journal of Science, Technology, Ethics and Policy*. 2011; 2:100-109.

Examples of Potential Projects:

- Developing advanced assistive techniques for the disabled.
- Transitioning assistive devices for other uses (e.g., cochlear implants that allow a normal wearer to hear beyond the usual human range).
- Developing advanced feedback mechanisms for training.
- Augmenting cognition, motor skills, senses, and creativity via neurotechnology.
- Improving human relational skills and insights.
- Transmitting knowledge directly, rather than through traditional learning methods; i.e., a recipient would be able to demonstrate knowledge of a text that they have not read.
- Recording a multi-channel experience of one person, and then "play it back" in another person.
- Creating useful transmissible semi-synthetic and artificial experiences.
- Advancing below-to-average human intelligence or memory to above-normal levels on a sustainable basis and in a proliferable manner.
- Advancing above-average intelligence or memory to "genius" level.
- Using nontraditional techniques to create new skills or capabilities in someone who was not taught or previously able to demonstrate that skill or talent.
- Creating credible just-in-time training techniques for rare but critical functions.
- Developing techniques to improve human emotional maturity and coping skills.

D. Synthetic Brains and Cognitive Computing

As all other areas of the Roadmap develop, the potential of computing initiatives based on the brain and cognition will continue to grow. Furthering basic understanding of the brain and cognition will feed development of computing and technologies modeled on these processes. Current efforts should be continued and expanded across other disciplines to improve cross-fertilization of ideas. General goals in this area are to create functional machines modeled on human cognition, and to create a computer representation of a human brain with high fidelity and high capability. Again, this will require a much greater understanding of cognition at both functional and structural levels.

- **Cognitive computing and augmented cognition research hold promise for future technologies.**

  Cognitive computing and augmented cognition are key investment areas that should expand in scope and application as the science and technology move forward. The first steps toward augmentation may include improved learning and memory tools that directly access the brain to improve learning, or human-machine interactions that can leverage the strengths of both (the human and the technology). In the future, traditional immersive virtual reality may be supplanted by synthetic experiences, and may be able to record or store experiences that can be passed on to others.

  Augmentation of humans, both mental and physical, will only become possible as sophisticated communications' interfaces with the brain develop, and the relation of brain signals to cognition is better understood.

- **Develop advanced computation methods for simulation of brain functions; develop a functional synthetic approximation of a brain.**

  Some researchers are pursuing the goal of a functional computational model of the human brain,[32] such as IBM's Blue Brain project. Brain-based devices and robotics also continue to develop rapidly. These projects will benefit from advances in many areas outlined in "Track 1: B. Advanced Computing, Modeling and Simulation," "C. Greater Understanding of Neural Structures and Functions," and "D. Theory of Brain and Cognition, Complex Systems Architectures."

- **Bio-Computing and the synthesis of neurons and chips will enable future enhancement capabilities.**

  Since the mid-1990s, there have been various attempts to model computing on identified neurobiological principles. Now known essentially as DNA Computing, the goal is to exploit the efficiencies and novelties that biological computing might afford. In turn, it may be productive to reverse this relationship to generate chips that could be implantable for purposes of restorative therapy, or even performance enhancement. This is particularly intriguing considering the prospects of nano-sized devices and their potential capability to self-assemble once implanted in rudimentary form in the brain, spine, or peripheral nerves. If we assume that computational efficiency (bits/sec/volume) will be achievable, and that the appropriate algorithms are derived for delivery to the chips, the remaining research will have to focus on the (considerable) difficulties of neural-chip interfacing (see Track 2: A. Brain Interface Technology).

- **Efforts in cognitive computing have the potential to revolutionize computing and robotics.**

  Existing programs in cognitive computing are part of a broader effort to make computing more resilient, more intelligent, more intuitive and more usable. These efforts should be continued toward the goal of using cognitive patterns to produce a neurotechnologically-derived revolution in computing.

Examples of Potential Projects:

- Developing digital surrogates for the brain's analog functionality.
- Combining pure digital and analog-by-way-of digital methods so that the computer or program can self-select which processes to use to optimally solve arbitrarily selected complex problems.
- Building a computer or program that features the best analog and digital techniques for problem-solving in a domain of interest, but that is not specific to a particular domain.
- Building a self-aware, self-repairing computer or program (e.g., that "knows" it is being attacked).
- Building a computer with "common sense" though combination analog/digital inference, rather than exhaustive decision trees.
- Simulating human capabilities, such as awareness of irony, or a demonstrated sense of humor.
- Creating digital entity that demonstrates human-like thoughts, dexterity, skills and emotions.

32. The quantity of computation required for a top-level functional simulation of the brain is estimated at 10^{17} calculations per second (cps). The amount of computation required for simulation of the brain's subneural nonlinearities is estimated at 10^{19} cps. The speed ratio between contemporary electronics and biochemical signaling of neuronal components is more than 1 million: 1.

IV. NEUROTECHNOLOGY: ETHICAL, LEGAL AND SOCIAL ISSUES (NELSI)

The rapid pace, breadth and depth of research and development in several of the constituent fields of neuroscience and convergent sciences and technologies (e.g., genetics, nanoscience, cyber- and computational technology), and their potential for explosive breakthroughs necessitates an analysis of the ethical, legal, social and political impacts that these technologies could incur. Analogous developments have shown that "game-changing" scientific advances, such as genetic engineering or stem cell research, can outpace the ability of social and governmental institutions to respond adequately, and public consternation can backlash to impede the orderly development of scientific applications. In light of these effects, it is important to assess the potential societal impact and reciprocal effect of social attitudes and concerns on the development and uses of neurotechnologies.

Neurotechnologies with Immediate ELSI Concerns

- **Deception Detection**
- **Remote/Covert Imaging, Civil Liberties, and Human Rights**
- **Stem Cell and Neurogenesis Research**
- **Brain Interface Technologies**

NELSI Concerns

- **Individual Privacy and Civil Liberties**
- **Safety and Security**
- **Inadvertent use/Misuse of Neurological Information**
- **Employment Bias/Discrimination**
- **Government Employment Selection**
- **Misappropriated Law Enforcement and Intelligence Collection**
- **Judicial Misuse of Neurotechnology**
- **Fear of Government Abuse**
- **Mind Control**
- **Neuroweapons**
- **Treatment versus Augmentation**
- **Augmentation, Enablement and Enhancement**
- **Human-Computer Interaction and Sentient Machines**
- **Equity, Fairness, Distribution and Access**
- **Individuality, Free-Will, and the Fundamental Essence of the Mind, and What Constitutes Normality, and the Human Being?**

Figure 11: List Outlining Major Technologies and Potential NELSI Issues.

Many of the potential issues outlined in this section, and in Figure 11 above, span a wide range, and will need to be addressed in a comprehensive way. To meet this challenge, the study team offers recommendations for what the Federal government can do to play an active role in the responsible development of neurotechnology and related policy, both internally and across the field.

This assessment will focus on broad categories of developing neurotechnologies, the issues that research and applications of these neurotechnologies are likely to generate, and possible strategies for mitigating and dealing with the impacts. Some of the potential issues and their solutions are common to more than one category of technology.

The two major areas addressed are the use of assessment technologies, such as neuroimaging and EEG-based and biomarker scanning, especially for cognitive applications such as deception detection, and the use of brain interface technologies that have augmentation applications. These two areas are likely to generate the most public concern and resistance in the near future, and will thus require the most immediate attention and address. Although the technology required to "read thoughts" is not yet possible, the ability to interpret neural images, scans, and wave patterns to determine function, reaction and recognition is developing now, and has many potential applications. The benefits of these applications are already being demonstrated in areas such as clinical diagnoses/prognoses and neuroprosthetics. While clinical use of brain interface technologies is growing, any use of these technologies beyond what is diagnostic or restorative will engender major debate. As well, it should be noted that research issues in brain repair are also likely to be among the first objections to emerge against neurotechnology, especially as related to the use of stem cells. Even though many of the ethical issues in this research are not specific to neurotechnology, we have found that the objections to embryonic stem cell research in neuroscience may both incur many of the same ELS issues, and may foster others, based upon the potential for neural tissue transplantation to affect dimensions of consciousness, capability and identity.

For the neurotechnologies reviewed below, coercive or surreptitious use has the greatest potential for negative societal impact, as derived from legal and ethical problems, and public perception. Any technology can be misused, regardless of the benefit it promises or the controls placed upon it. Neurotechnology, however, because of its unique characteristics to engage the brain to affect cognition, emotion, the sense of self and behavior, may make it a particularly volatile area of public concern, especially if there is not a successful attempt at public relations, discourse and education, which must be accompanied by a substantive framework for addressing these issues.

Neurotechnologies with Immediate ELSI Concerns

- **Deception Detection**

The application of neuroimaging technology to detect deception has already evoked questions regarding privacy, civil liberties, legality, and ethics.[33] The immediacy of the concern is due to the relative maturity of neuroimaging technology, even if the science of its use for deception detection is still nascent. The American Civil Liberties Union (ACLU) and other civil rights organizations have already expressed serious concerns about deception detection; immediate steps should be taken to address these concerns.

Neuroimaging holds the promise of a more accurate methodology for detecting deceit over current polygraphy devices, which rely on autonomic responses to questions to reveal anxiety or nervousness about prevarication. The capability of neuroimaging to show activity in brain centers associated with communicating falsehood may prove more accurate than sensing perspiration, heart rate, and other autonomic functions.

It is very likely that neurotechnological deception detection will surpass current polygraphy both in "hit" rates and in "false alarm" management. Current polygraphy relies on the finding that conceiving or articulating a lie in the central nervous system creates discomfort, and that this discomfort can be detected by interrogating the autonomic nervous system (a part of the peripheral nervous system) through responses of respiration, galvanic skin activity, etc. Neurotechnology-based deception detection is aimed at direct assessment of central nervous system functions to depict neural correlates of cognition and emotion reflective of truth-telling or deception. Research is already demonstrating an ability to discriminate brain activities of truth or deceit, just prior to and during production of a response. These laboratory-controlled studies of neurotechnology demonstrate that it holds promise, particularly because the tests depend on direct brain activity instead of indirect measures of stress and other secondary signs. However, it is uncertain whether the isolated and simple lies performed by normal subjects in a lab will correspond to real-life situations where lies may be more complex, have deeper emotional stakes, or subjects may be uncooperative or mentally unstable.

Many of the criticisms that have been made of polygraphy can also be leveled at use of neuroimaging for deception detection. The traditional polygraph is largely considered unreliable and seldom admitted as evidence in court. Commercial and academic claims of accuracy for fMRI-based deception detection approach 80-90 percent.[34] However, the studies on which these claims are based have no standardized method for testing for deception, and are based on simplistic lies, such as what playing card a subject is holding, that may not be cognitively equivalent to more complex or high-stakes deception, as in a murder case. It is unknown whether neuroimaging methods of deception detection, like the polygraph, could be "fooled" by a dedicated, practiced liar or a sociopath. An objective observation of activity or

33. Incidental findings of current or possible disease from non-medical neuroimaging also raise ethical and legal questions. However, a body of guidelines exists to address these issues as they currently arise in clinical and research settings, to they will not be discussed at great length here.

34. Pearson H. Lure of lie detectors spooks ethicists. *Nature*. 2006; Jun 22;441(7096):918-9.

lack of activity in brain networks involved in lying may not mean the subject's answers are the truth. In cases of mentally ill or delusional subjects, the person may have created a separate mental world or have a system of beliefs that affect their perceptions. Even if a person can be shown via neuroimaging to be telling what they believe to be true, they may have simply misperceived the truth.

The increased perception of scientific objectivity or authority of neuroimaging methods may give undue credence to the results of these approaches before they are fully understood. In this sense, neurotechnology is distinct from other forms of deception detection, such as the polygraph. The invasive nature of visualizing someone's brain function, taken with the perceived objectivity and authority of neuroscience, may combine to make subjects unable to effectively defend themselves from faulty testing or false-positive findings. This perceived authority of neuroimaging methods may also unduly affect jury and/or judicial decisions, especially as the technology gains wider exposure in the popular press. We advocate that unless and until neuroimaging can be scientifically proven to be accurate for deception detection, these methods should be viewed with scrutiny so as to maintain a level of doubt regarding their current acceptability for many legal and governmental purposes.

Discussions with civil liberty advocates regarding all neurotechnologies repeatedly gravitate to the use of neuroimaging for deception detection, especially in legal, employment and even civil contexts. Concerns include the reliability and accuracy of use for this purpose (in court or otherwise), as well as impacts on privacy, and incurring possible discriminatory practices. The concerns voiced are immediate, since commercial development of neuroimaging-based approaches to deception detection is occurring now. The ethical, legal and social concerns outlined above are likely to become manifest in the next few years. Moreover, if the concerns are not addressed proactively, civil liberty advocates, and the public, could take measures to limit further research and this could adversely affect the more positive aspects of developing neuroimaging and other neurotechnologies.

A framework for the mitigation of these potential impacts already is in place, however, more meaningful engagement with policymakers, legislators, bioethicists, neuroscientists and advocacy groups will be required to address, analyze and govern research and use of these neurotechnologies. While the Federal Rules of Evidence prevent the introduction of expert testimony (such as that of a neuroscientist) on the subject of deception detection, unless the testimony is based upon "reliable principles and methods,"[35] these standards change as a consequence of increased and diversified use, and the expanding field and applications of neuroimaging – and related technologies – have and will incur iteratively more ethico-legal debate and contention. This is a very important issue as the discipline of "neuro law" has emerged as a major domain of NELSI. A host of governmental and private funding investments devoted to supporting these incentives can be found in the U.S. (Stanford University, CA, University of Notre Dame, IN, and Baylor College of Medicine, TX) and in Bonn, Germany (Friedrich Wilhelms Rheinische University).

We assert that neuroimaging for deception detection should not be used in a judicial setting unless and until the reliability and accuracy approaches one hundred percent. It is likely, however, that these technologies will enter the courts before this is achieved. Active engagement with advocacy groups, attorney groups (including judges), policy-makers and legislators could avert negative impacts and results. As the field and its technologies expand, a dedicated working group of these stakeholders and

35. Federal Rules of Evidence, Rule 702.

representatives of the research community should be committed to ongoing review of applicable laws, regulations and court rules to ensure that the protective framework that currently exists extends to the use of neuroimaging for deception detection, employment purposes, insurance screening, court procedure and privacy.

- **Remote/Covert Imaging, Civil Liberties, and Human Rights**

The current state of neuroimaging technology requires cooperation by the subject, but remote imaging and surreptitious employment of such sensors for covert sensing is imaginable in the future. Such covert use of imaging increases the complexity and broadens the scope of these issues, impacting First, Fourth, Fifth, Sixth and Fourteenth Amendment, and various privacy and confidentiality rights. These are not limited to deception detection. Transportation security agencies are investigating the ability to read ill intent as people wind their way through security checkpoints, without having to physically yoke them to a scanner.[36] If remote sensing were available, a marketer could monitor the reaction of a potential buyer to a merchandise display without the buyer's knowledge. Contract negotiators could perhaps detect when a counteroffer is actually acceptable or when the other party is bluffing. While the legitimate and open uses of remote imaging could be beneficial, surreptitious use could engender some of the same controversy as Radio Frequency Identification (RFID) technology.[37] Regulation and prohibition of unauthorized electronic eavesdropping and wiretapping may provide a legal framework for use of such technologies, especially where there is an expectation of privacy in verbal and written communications.[38]

The potential use of neuroimaging and neurobiomarker assessment for detecting deception in prisoners of war and illegal enemy combatants raises questions of international law and how the practice would be perceived on the global stage. The Geneva Convention[39] protects persons falling within the definition of a prisoner of war from cruel treatment and torture (Article 3) and from scientific and medical experiments that are not justified by the prisoner's condition (Article 12). Neuroimaging of prisoners of war may be coercive in nature, but it does not seem to fall under the rubric of cruel treatment or medical experimentation. Indeed, more accurate deception detection techniques may reduce the pressure on intelligence gatherers to use severe interrogation techniques or torture. Nevertheless, the use of neuroimaging and/or biomarker evaluation beyond traditional medical purposes by scientists and medical professionals may spur international controversy, especially if these approaches discover some condition of the prisoner or detainee that can be psychologically exploited for intelligence purposes.

- **Stem Cell and Neurogenesis Research**

Projects employing stem cell research, especially embryonic stem cell research, in neuroscience are likely to suffer the same scrutiny and debate as all other stem cell research, and must be carefully handled to prevent derailment of the research. Neurotechnology research involving stem cells, and

36. Kluger J. "How to spot a liar." *Time*. August 20, 2006. http://www.time.com/time/magazine/article/0,9171,1229109-1,00.html.
37. Several states have passed legislation regarding the use of RFID tags on commercial products and packaging. Worldwide, privacy advocates have protested the use of RFID, especially where there is no notice to the consumer.
38. Wiretap Act, as amended by the Electronic Communications Privacy Act of 1986, 18 U.S.C. §§ 2510-2522. Such an expectation of privacy is apparently recognized for written communications over the Internet. See *U.S. v. Councilman*, 373 F.3d 197 (1st Circuit 2005).
39. Diplomatic Conference for the Establishment of International Conventions for the Protection of Victims of War. *The Geneva Convention Relative to the Treatment of Prisoners of War*, adopted August 12, 1949.

possibly neurogenesis and transplantation of brain cells, is incurring a greater degree of scrutiny from groups already mobilized against stem cell research. This opposition may affect the ability of scientists to pursue certain areas of research. It is essential to prevent general research on neurogenesis and brain tissue regeneration from getting mired in the stem cell debate, as this could have a serious chilling effect on the overall research, which will be key to many clinical uses. It is possible that as advances emerge, public support for stem cell research will shift and this will be less of an issue, but for the present, the anti-stem cell research movement is highly active in opposing many of these efforts.

Future treatment possibilities for treating neural disorders and injury also include re-growing neural tissue to repair or replace damaged areas of the nervous system. Scientists recently discovered that adult neurogenesis occurs naturally in certain parts of the brain. Drugs and other interventions may be able to stimulate neurogenesis as a cure for degenerative diseases, though the technologies based on this process may take several years to be perfected. The potential, however, is enormous, both for repairing damage to human brains, and applying techniques and technologies to stimulate neurogenesis for other purposes, including augmentation of cognition emotion, and/or behaviors. Several issues may arise from research and applications of neurogenic techniques and technologies, and the use of neuro-potential stem cell research and experiments or transplants of human brain cells are generating significant controversy.[40]

An ongoing issue of public resistance to neurotechnology may be the research and use of brain cells for repairing the nervous system. The national debate on stem cell research influences these postures. A majority of Americans agree that stem cell research would be valuable for medicine,[41] but a vocal minority has moral and religious objections to embryonic stem cell research. As a result, Federal funding for this research has been severely restricted, despite a bipartisan bill to expand funding which ended in the only veto of George W. Bush's Presidency.[42] Stem cells derived from both embryonic and adult sources hold great potential for research on neurogenesis. Research on adult cells also could encounter some resistance, as the idea of artificially growing new brain cells, or transplanting them between individuals, may be disturbing as it relates to issues of personal identity.

Human embryonic stem cell research provides a case in point for proactive policy on ELSI. After years of public debate and controversy on the subject, the federal government restricted the use of government funds for embryonic stem cell research in 2001. In 2005, the National Academies of Science (NAS) published *Guidelines for Human Embryonic Stem Cell Research*, which attempts to balance the scientific community's desire to pursue the research against public concerns about reproduction and

40. (a) Giordano J. Neuroethical issues in neurogenetics and neurotransplantation technology – the need for pragmatism and preparedness in practice and policy. *Studies Ethics, Law Technol.* 2011; 5(1). (b) Boer GJ. Transplantation and xenotransplantation. In: Giordano J, Gordijn B. (eds.) *Scientific and Philosophical Perspectives in Neuroethics*. Cambridge: Cambridge University Press, 2010, p. 190-216.

41. A variety of polls have shown that a majority of Americans, up to 68%, favor federal funding for embryonic stem cell research. *PollingReport.Com Compilation of Science and Nature Poll Results, 1999-2006*. http://www.pollingreport.com/science.htm. Viewed February 20, 2007.

42. The ultimate impact on embryonic stem cell research is unclear, however, with a recent influx of state and entrepreneurial funding including a $3 billion initiative from the State of California. Bailey R. "Americans Vote Pro-Life: Did stem cells give the Senate to the Democrats?" *Reason Magazine*. November 10, 2006. http://www.reason.com/news/show/116645.html.

appropriate use of embryonic stem cells.[43] Their key recommendations include a dual system of oversight at the institutional and national levels, which would establish an Embryonic Stem Cell Research Oversight (ESCRO) committee at any institution conducting human embryonic stem cell research, in addition to an Institutional Review Board (IRB), which would ensure careful oversight in traditional areas of experimental designs and objectives, informed consent, and protection of donor information. They also recommend careful oversight of procurement procedures, informed consent of donors, and adherence to existing regulations relevant to the research. If this framework had been in place prior to the issuance of the federal policy, it is possible that the policy would not have been needed.

Many of these recommendations can be adapted to brain cell research and to neurotechnology research in general. An institutional oversight body, separate from an institutional review board at both the research institute and national levels, would be an avenue to ensure proper application of research standards. Such procedural guarantees may help assuage public fears about neurotechnology, but are not likely to do so entirely.

Mitigation strategies for potential public issues related to brain and stem cell research largely rest on public education about the value of this research to patients, including soldiers, who suffer from brain injuries or neurodegenerative disease. Positive examples include Michael J. Fox's foundation to raise awareness and funding for Parkinson's disease research, and Christopher Reeve's impact on spinal cord injury (and stem cell) research.[44] Individuals can clearly be seen as being helped by this research, and this can have a strong impact on public opinion. Still, stem cell or brain cell research by the government and defense agencies may especially be seen as potentially fraught with ethical issues. It is important to focus these efforts on clinical applications that can have direct benefits to patients and soldiers with brain injuries, paralysis, prosthetic limbs, and other conditions related to the central nervous system. Even so, the benefits of stem cell research have not overridden the moral and religious objections to the research methods using embryonic tissue, and there will be limitations on how much public education and information can achieve in light of longstanding views and biases. This is important to note as there have been advances in non-embryonic, autologous stem cells that have been offered as a side-step to the issue at large.[45]

- **Brain Interface Technologies**

The prospects of returning a person (whether a civilian or soldier) with a brain injury to a full life, of providing sight to a visually impaired person, and of boosting a student's ability to excel, will continue to drive direct brain-computer interface and augmentation research, development and applications. Brain interface technologies allow a direct connection between the brain and a computer, machine, or assistive device. The technology is still in the early stages of development, and many key areas of basic understanding and engineering must be overcome.

43. Committee on Guidelines for Human Embryonic Stem Cell Research, National Research Council. "Guidelines for Human Embryonic Stem Cell Research." 2005. http://www.nap.edu/openbook/0309096537/html/index.html.

44. Christopher Reeve Foundation. "CRF Position Statement on Stem Cell Research, 2005." http://www.christopherreeve.org/site/c.geIMLPOpGjF/b.1098167/k.7502/CRF_Position_Statement_on_Stem_Cells.htm. Viewed February 20, 2007.

45. Yu J, Vodyanik MA, et. al. Induced pluripotent stem cell lines derived from human somatic cells. *Science*. 2007; 21(318): 1917-1920.

Technologies currently in clinical use, however, are being used to interface with the brain in basic ways to treat neurodegenerative disease and provide assistance to patients with severe disabilities. In the future, as engineering and understanding of the brain improve, these technologies will allow far more advanced interaction with the brain. With this increased capability will come major issues of what the technology should be used for, who should be able use it, how access to an individual's mind can be controlled, and to whom such technologies will be provided. As these capabilities develop, society will have to determine where the line between repair to normal function and augmentation lies, and how an individual's ability to use these enhancing technologies will be regulated.

Brain interface technologies are now able to process the brain's signals into usable instructions for an external device, such as a prosthetic arm or a cursor on a computer screen. These assistive devices are used by patients with paralysis or severe disabilities to help them communicate and to restore some of their motor function. In the future, more advanced versions of these technologies could enable both disabled patients and normal ones to send signals from their brains to a variety of external devices. Another category of brain interface technology currently in clinical use sends simple signals into the brain to help control condition or dysfunctions such as epilepsy, Parkinson's disease, and severe depression. Deep brain stimulation (which, despite significant progress in refining technologies and techniques, is still at a fairly rudimentary level) operates by sending electrical signals into the brain to regulate signaling via a small number of electrodes that target large numbers of neurons. As scientists gain a greater understanding of how brain signals lead to behaviors and are disrupted in diseases, and as the engineering of electrode arrays improve, this technology could potentially be used for regulation of many other brain functions. Potential applications include treatment for alcoholism and drug addiction, aggression, violence, and other forms of mental illness. The ability to alter mood or behavior via an internal or external device could have profound implications for safety, security, privacy, individual choice, and the legal and penal systems.[46]

Appropriate use of brain interfaces and neural implants, as well as their safety and efficacy, is currently regulated by the Food and Drug Administration (FDA). Future medical uses of the technology would most likely fall under that agency's jurisdiction. An institutional oversight body, either at the institutional or funding-agency level, may be the best mechanism to ensure ethical and proper application of technologies for enhancement in the near term.

NELSI Concerns

- **Individual Privacy and Civil Liberties**

  As understanding of the brain and neurotechnology advance, individual privacy and the security of personal information will become increasingly important. Individual control of one's cognition, consent requirements for the collection and release of information, and the privacy of information are all key requirements. Intellectual property issues may also emerge as machines emulate individuals or an individual's cognitive functioning becomes more public.

46. Jotterand F, Giordano J. Deep brain stimulation and transcranial magnetic stimulation: Personal identity, ethical questions and neuroethical approaches in clinical practice. *International Review of Psychiatry*. 2011; 5.

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Human thought and cognition are more or less private, and today we can control who has access to them. In the future, however, neurotechnology may enable unprecedented access to information about the functioning of the brain. Regulating access to this information will be key: neuromarketing (already a flourishing field), insurance coverage or denials, and discrimination could be serious consequences of improper access to this information. A good (if insufficient) analogy is the privacy regimen for HIV/AIDS status, or genetic screening. For example, early screening for neurodegenerative diseases or mental illness could result in discrimination, insurance rejections, etc. One can easily imagine a court-ordered deception detection device or "intention monitor" applied to paroled prisoners or sex offenders.

Neurotechnology R&D by the government may also lead to fears of government compiling information on citizens' brains and cognition, or even mind-reading and mind control.

- **Safety and Security**

  In the near term, safety of neurotechnology devices (e.g., brain-computer interface devices) will be a primary concern; existing regulations on the safety and efficacy of biomedical devices may need to be extended or revised to cover new technologies. Security of personal information obtained via neurotechnology will also be an important issue; again, privacy standards such as HIPAA for medical data may need to be extended to cover data use outside the usual medical realm. In the future, the brain and its cognitive processes may be easily readable, via connections to the internet or other devices. Safety and security measures will be essential to ensure privacy and to prevent intrusion, hacking, virus infection, manipulation, identity theft, or other unauthorized outside access.

  A primary issue with any technology that directly interfaces with the brain would be safety and reliability, especially as the side-effects or long-term effects of a technology could be unknown until many years later. Public demand for the technology could swell before these risks were known, in which case it may be difficult for regulatory bodies to restrict their use (for example, several pharmaceuticals have been shown to be safe in clinical trials, but have long-term or more subtle effects that are not realized until they are in public use). It is also possible that such technology-induced effects would not be as easily controlled by the user as normal brain function; with current understanding of the brain, "it is unclear whether we have any control over what we remember. If we do, would brain implants of the future force some people to remember things they would rather forget?"[47] Basic safety questions will arise on procedures and devices.

  "Safety and efficacy" are the standards for FDA approval of medical devices, which currently covers medical brain interface devices. Existing human trials' standards and Institutional Review Boards will be able to address basic safety issues of development and testing of devices. These entities, however, are designed to evaluate technologies for medical use, and may not be equipped to address larger ethical and regulatory issues that may arise as neurotechnology transitions from use in medical contexts to broader or elective use. For non-invasive testing, and testing or services performed by private companies, IRBs may not have any jurisdiction or control over the actions of a private company, that does not choose to follow their guidelines.[48]

47. Graham-Rowe D. "World's first brain prosthesis revealed." *New Scientist*. March 12, 2003. http://www.newscientist.com/article.ns?id=dn3488.
48. (a) Giordano J, DuRousseau D. Toward right and good use of brain-machine interfacing neurotechnologies: Ethical issues and implications for guidelines and policy. *Cog. Technol.* 2011; 15(2):5-10. (b) Plischke H, Du Rousseau D, Giordano J.

Security and privacy of brain augmentation could become major issues as computers and biological components become more closely intertwined. If the brain directly interfaces with a computer or other device that can regulate input or output signals, how can the security of such a device be ensured? If an unauthorized party could access the brain via these devices, the brain – or perhaps more accurately, consciousness and people themselves – could be vulnerable to hacking. Could computer-like viruses effectively "infect" a human brain, inflicting damage far beyond what is imaginable today? The concept of identity theft becomes even more threatening when it could potentially mean hacking into actual thoughts and memories rather than just electronic data. Hacking could become a crime against person and not just a crime against property. The government, and the public, will want even more protections against "mind-hacking" than they do against computer crimes.

The issue of security also relates to general fears of "mind-reading," either by a government or some private entity. The concept of a government spying on its citizens is not specific to neurotechnology, but the potential capability of neurotechnology to tap directly into someone's thoughts, perhaps even without their knowledge, or the ability to mediate what is seen, is profoundly disturbing. Who will be allowed access to the devices and their contents or archives? A person is protected against self-incrimination, but this does not protect all documents and records. Will – and how should – these devices and any archives of thought or reaction be protected?

- **Insurance**

In the judicial setting, a judge is present to adjudicate the balance between competing interests. However, as we have found, in the business, employment, education and other public use arenas, the fairness of neuroimaging applications are more subjective and open to overreaching claims.[49] Insurance companies are likely to be very interested in the capability of neurotechnology to verify the accuracy of information supplied by an applicant or to indicate a propensity to develop neurodegenerative diseases, addictive disorders, or mental illness. Since the insurance company and the applicant are not usually in equal bargaining positions, the applicant may not be able to refuse scans for either or both purposes. Even if there is a strong social reason to ensure that insurance applications are honest and accurate, should the denial of insurance be based on the possibility of developing a disease?

Predictive genetic testing for disease markers provides an analogous case.[50] The Health Insurance Portability and Accountability Act (HIPAA)[51] and the Genetic Information Nondiscrimination Act (GINA)[52] provide some protection against insurance companies discriminating against individuals based on their health history and predispositions, but this most protects individuals from being denied coverage altogether. Both HIPAA and GINA state that genetic information shall not be treated as having a condition in the absence of a diagnosis. HIPAA does not, however, prohibit using genetic information as a basis to charge a category of consumers or group more for health coverage, and does

EEG-based neurofeedback: The promise of neurotechnology and need for neuroethically-informed guidelines and policies. *J. Ethics Biol Engineer Med.* 2012; 4(2):7-18.

49. Giordano J, DuRousseau D. Toward right and good use of brain-machine interfacing neurotechnologies: Ethical issues and implications for guidelines and policy. *Cog. Technol.* 2011; 15(2):5-10.

50. Greely, Henry T. "Neuroethics: The Neuroscience Revolution, Ethics, and the Law." Regan Lecture, Santa Clara University. April 20, 2004.

51. 42 U.S.Code 1320d-1329d-8 (1996); Pub. L. 104-191; 110 Stat. 2021-2031.

52. 42 U.S.Code 2000ff (2008); Pub. L. 110-233; 122 Stat. 881-922.

not specifically prohibit genetic testing. HIPAA preempts state regulation (since states are traditionally accorded the responsibility for insurance regulation), but it does not preclude states from enacting more stringent requirements. According to the National Conference of State Legislatures,[53] over forty states have enacted some provision that prohibits denying coverage on the basis of genetic testing, and many regulate whether or how insurance companies may charge more based on genetic testing, though these provisions vary widely from state to state.

Brain imaging data are already a part of patient medical records, but new questions about how data are used may arise as scientific understanding of the brain is advanced. Legal principles and precedents exist for extending state and Federal protections to prevent discrimination based on neurotechnology findings, but in the absence of an amendment to HIPAA or other Federal regulation, the regulation of the use of neuroimaging by insurers will be left to the states. In addition, existing HIPAA rules for subpoena and government access to medical records may need to be re-addressed and extended.

- **Employment**

  Employers want to know the veracity of employees and potential employees, so the higher level of accuracy in predictions of behavior, and assessments of deception promised by neuroimaging will be attractive. Currently, outside of governmental employment, the use of polygraph machines are limited and regulated by the federal Employment Polygraph Protection Act (EPPA). This Act prevents civilian employers from using lie detectors in pre-employment determinations and during the course of employment. In addition to polygraphs, the definition of lie detector includes "any other similar device (whether mechanical or electrical) that is used...for the purpose of rendering a diagnostic opinion regarding the honesty or dishonesty of an individual."[54] Neuroimaging, for that purpose, appears to fall within the ambit of EPPA.[55]

  EPPA seems to encompass neuroimaging for deception detection within its definition of a "lie detector," but ongoing developments in the field of neuroimaging, coupled to existing claims of certain firms offering fMRI-based behavior screening, support that the Act should be reviewed and revised to update provisions that apply to polygraph tests administered by governmental entities for security purposes. Other legislation and regulations include prohibitions against discrimination on the basis of information that would be revealed in neuroimaging, regardless of the reason for administering the tests. Such protections exist for employees, students, the disabled, and other individuals, and include the Americans with Disabilities Act (ADA), the Individuals with Disabilities Education Act (IDEA),[56] and Title VII of the Civil Rights Act of 1964 (as amended).[57] If neuroimaging is used for other legitimate pre-employment testing (e.g., to show language aptitudes), protections may be needed against the intentional or inadvertent discovery of attitudes or a predisposition for disease. A review of existing law may be needed to identify potential gaps and to add protections as neuroimaging emerges for such purposes.

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53. National Conference of State Legislatures. "Genetics and Health Insurance: State Anti-Discrimination Laws." http://www.ncsl.org/programs/health/genetics/ndishlth.htm. Viewed February 20, 2007.
54. 29 U.S.Code 2001; 102 Stat. 646; PL 100-347 (1988).
55. Neuroimaging may fall under EPPA without amendment, but other sections should be reviewed, such as the qualifications for a polygraph examiner.
56. 20 U.S.Code Sec 1400 (1997); P.L. 105-17 (1997).
57. 42 U.S.Code Sec. 2000e (1964); P.L. 102-166 (1964).

- **Government Employment**

Government employers, however, are exempt from EPPA and may use polygraphy for personnel screening purposes. As neurotechnology for deception detection develops, some government employers may push to move toward this technology and away from the use of polygraph tests for investigations and interrogation for security clearances. Issues of accuracy and reliability will have to be resolved before the government transitions to neurotechnology testing, although similar issues exist with polygraphy and it is used nonetheless. If neurotechnology methods can be shown to be more reliable than polygraphy, it may be advisable to make this transition. However, such a move would likely be resisted by members of government and the public, and would certainly engender public debate on the merits of the technology.

If governmental entities or other employers begin to use neuroimaging and/or neurogenetic screening for pre-employment or course of employment examinations, the incidental discovery of disease or precursors of disease would raise additional questions that traditional polygraphs do not. Pre-employment scans could determine the potential for developing a disease or a propensity for violence or a criminal act. Should these possibilities be used as the basis of employment decisions? Again, existing law and policy can provide some precedent, but may need to be extended or revised to include new technologies.

Declining to hire someone on the basis of a potential disease or disability would transgress employment discrimination laws such as the ADA.[58] In conjunction with GINA, over thirty states have provisions that prohibit genetic discrimination in the workplace. Executive Order 13145 prohibits genetic discrimination against federal employees in the workplace. Firing, reassigning or taking some other employment action based on the incidental findings of imaging also raises employment discrimination and constitutional tort questions. These same issues apply if the scanning or imaging technology is not used for deception detection, but for alertness monitoring or other purposes that may reveal some abnormality. In such cases, the employer's obligation to inform the subject, and perhaps provide treatment, will emerge as both ethical and liability issues.

Governmental entities should adopt policies regarding incidental findings if and when neuroimaging, neurogenetics and/or neuro-biomarker assessments for security or other purposes are used. Current workplace protections against discrimination and use of polygraphs should also be extended to cover such neurotechnologic applications.

- **Law Enforcement and Intelligence Collection**

Even outside evidentiary questions, neuroimaging could be used in other law enforcement, intelligence, business, and domestic contexts with implications for privacy, confidentiality, civil liberties and other legal rights. Police, law enforcement officers and intelligence personnel will be keenly interested in these new tools to provide a compass through the thicket of investigation and interrogation, especially if it is perceived that neuroimaging is more accurate than polygraphy.[59] In addition to deception detection, these technologies will assist in determining if a subject recognizes or is familiar with an object, face or word.

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58. 42 U.S. Code 12101; PL 101-336 (1990).
59. Kalbfleisch ML, Forsythe C. Instantiating the progress of neurotechnology for applications in national defense intelligence. *Synesis: A Journal of Science, Technology, Ethics and Policy.* 2011; 2:92-99.

Polygraph tests require cooperation and volition. The person has to be attached to the sensors, remain still, and answer the questions. In neuroimaging, the person likewise has to agree and cooperate, and stay motionless during the procedure. Most current technology requires subjects to answer yes-or-no questions by pressing a button, because speaking, or even eye movement, would disrupt the imaging. If there is coercion to cooperate and submit to the testing, constitutional and legal ramifications arise. The coercive techniques could include threat of prosecution of the subject (or someone close to the subject) the promise of leniency, and any number of other schemes that are depicted with regularity in film. In addition, the nature of neurotechnology is more invasive, since neuroimaging literally "looks inside" the brain and bypasses the mediation of speech. Potential tests using neurotechnology could detect a subject's brain's recognition of an image, which could incriminate them even if the subject is never asked about it or given a chance to respond.

Civil liberty and privacy advocates have already expressed a desire for additional protections from this type of deception detection testing and may seek these protections legislatively and in the courts in the near future.

- **Judicial System**

The perceived objectivity and authority of neuroimaging and other brain scans may drive an attempt to have the results of lie detection tests introduced as evidence in court. Presumably, the courts' disposition of polygraph results would be extended to brain scan deception detection even without an amendment to the Rules of Evidence or pretrial procedure. Simple rulings of relevance (i.e., Frye-type standards) are no longer adequate or sufficient to guide the potential use of neurotechnology in judicial cases. The procedural rules for reliability established under *Daubert v. Merrill Dow Pharmaceuticals*[60] (i.e., Daubert standards) should apply to experts testifying on neuroimaging and other neurotechnoliogically-based claims to reveal deceit capability or infer culpability, but the science of neurology, neuroimaging and neurogenetic screening is far more established than polygraphy, even if the science of detecting deception (and/or potential culpability) is not perfect. Admission of such expert testimony into evidence is conceivable, especially due to the greater perceived authority of neuroscience methods. This issue has grown enormously. It is no longer simply a question of deception detection, but rather the use of neurotechnology to predict certain behavioral patterns, define capability and infer culpability.[61] These trajectories of research and use require a funded program of address, analysis and rectification/governance, both for use here in U.S.A. and in international courts.

Another form of neurotechnology, referred to as "brain fingerprinting," is based on P300 brain waves, which indicate whether a person recognizes an image or information. This technique was ruled admissible but not sufficient evidence by the Iowa District Court in the murder case of Terry Harrington, and the Iowa Supreme Court later overturned his conviction in 2003 on a procedural

60. *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

61. (a) Jotterand F, Giordano J. Real-time fMRI – brain computer interfacing and the assessment and treatment of psychopathy: Potential and challenges. In: Claussen J. (ed.) *Springer Handbook of Neuroethics*. NY: Springer, 2013. (b) DeBacker D, DeBacker D, Giordano J. Deliver us from evil? On the utility and neuroethico-legal issues of predictive neurotechnologies. *Theoret Medicine Biol.* 2013; 15.

basis.[62] The company conducting these tests has received attention and funding from the Federal Bureau of Investigation (FBI) and Central Intelligence Agency (CIA), and is aggressively marketing them to states for use in their judicial systems.[63]

Other uses for neurotechnology in the judicial setting could also appear. Neuroimaging for deception detection could be used during *voir dire* to ensure that potential jurors were in fact truthful, that they did not recognize the participants or know about the case, and that they were not biased or prejudiced about the particular case. Verification of jury impartiality is now limited to restricted background investigation and monitored questioning in court. Even the judge could be challenged on impartiality incident to a motion to recuse. While it is unlikely that any court would rule that these were appropriate uses, it could be legislated if the techniques were ever deemed to be accurate enough. Service on a jury is considered a duty. Would this mean a mandate to submit to (neurotechnological) deception detection in the same way that an oath to tell the truth is required for juries? These applications are further down the road, but need to be addressed both now and in the future.

The *Daubert* line of cases require a judicial assessment of the scientific soundness of expert testimony, but to prevent the confusion of the science of neuroimaging with the methodology of using it for deception detection, specific legislation and judicial rule making could proscribe the use in court until the reliability and accuracy of the methodology could be scientifically established. With regard to the utilization of neuroimaging deception detection for other purposes in the judicial setting, such as for jury selection or sentencing, it is unlikely that such judicially made rules would be established if the rules for expert witnesses and other rules of evidence did not permit the use in open court.

- **Fear of Government Abuse**

  Applications such as deception detection and identification of neurological markers for mental illness, addiction, or other characteristics could profoundly change the legal system. Many people already fear government intrusion into private life, and government use of neurotechnology may be seen as an attempt to observe or control citizens. Military use of neurotechnology may be fiercely resisted, even if it conforms to existing standards regulating warfare, weapons, treatment of detainees, etc. Citizens may fear that governments will use the technology against them, or use it to intimidate, coerce or torture prisoners of war (even if these actions are outside the normal standards of conduct- reference the Abu Ghraib abuses). Strong regulations must be put in place to prevent misuse or abuse. Opposition to neuroimaging-based deception detection has already coalesced, primarily on the grounds that the science is not yet advanced enough for it to be reliable.[64]

62. *Terry J. Harrington vs. State of Iowa*, Iowa Supreme Court Ruling, No. 122 / 01-0653, February 26, 2003. http://www.judicial.state.ia.us/Supreme_Court/Recent_Opinions/20030226/01-0653.asp?search=brain%20fingerprinting#_1.

63. Dale SS. "Climbing inside the criminal mind." *Time*. November 26, 2001. http://www.time.com/time/magazine/article/0,9171,1001318,00.html.

64. (a) Giordano J, Wurzman R. Neurotechnology as weapons in national intelligence and defense. *Synesis: A Journal of Science, Technology, Ethics and Policy*. 2011; 2:138-151. (b) Forsythe C, Giordano J. On the need for neurotechnology in the national intelligence and defense agenda: Scope and trajectory. *Synesis: A Journal of Science, Technology, Ethics and Policy.* 2011; 2(1):5-8. (c) Giordano J, Forsythe C, Olds J. Neuroscience, neurotechnology and national security: The need for preparedness and an ethics of responsible action. *AJOB-Neuroscience.* 2010; 1(2):1-3.

Government researchers will need to consider ethical issues like incidental findings and obligations to provide care. For example, if a brain tumor is found in a prisoner when brain imaging is used for information-gathering or deception detection, what is the government's obligation to inform the prisoner or provide care?

- **Mind Control**

A frequent extrapolation of the capabilities of neurotechnology is the idea of mind control. When the results of experiments are published that indicate the ability to stimulate the brain or read neural signals, headlines often declare that mind control is "just around the corner". For example, popular press articles on rat neurons flying a simulator, "robo-rats" with electrodes in their brains being controlled through a maze, and a neural prosthesis allowing a paralyzed man to move a cursor or arm with brain signals, all use "mind control" as a cultural reference point.[65] Articles about researchers' ability to predict behavior in a lab setting (for example, a subject's decision to add or subtract presented numbers) is inevitably extrapolated to visions of "Minority Report"-esque ability to see complex future actions (such as murder). News reports about altering moods or thought processes can have the same result.

The tendency of the popular press to be overly optimistic about the capabilities of neurotechnology may lead the public to believe that neurotechnology is far more advanced than it actually is, and it may generate fears that the technology will be used for purposes in the near term that are not actually plausible. This idea of "neuro-realism," posited by Eric Racine, Ofek Bar-Ilan, and Judy Illes, suggests that coverage of neuroscience research "can make a phenomenon uncritically real, objective, or effective in the eyes of the public."[66]

Public concern may increase, and new ethical, legal and social issues may develop, as brain interface technology allows more direct reading of brain signals and allows input of signals into the brain. While it may never be possible to externally control a person's mind or read someone else's thoughts, real issues of individual control of the mind will arise from neurotechnology, specifically brain interface technology, in the near future. The fundamental issues will center on privacy of thought and potential for "mind control." The impacts, therefore, will emanate from the technology and from the perception that the technology could be used for nefarious or socially objectionable purposes (irrespective of technical impossibility or practical implausibility).

The impacts will be intensified in those instances where the government, military and perhaps big business are developing or deploying neurotechnologies, since this tends to raise Orwellian allusions. The capability to use technology to boost the cognition, intelligence, and speed to decision by military leaders may raise visions of super humans and cyborgs. Use against military enemies may also generate resistance from international human rights organizations, especially after recent abuses. Potential use by homeland security and law enforcement officers domestically may magnify concern and fear.

Motor control devices that today allow paralyzed patients to move an assistive device could one day be used to input motor signals instead of reading output from the brain, casting visions of a person strung

65. Racine E, Bar-Ilan O, Illes. J fMRI in the public eye. *Nature Reviews Neuroscience*. 2005; 6:159-164.
66. *Ibid.*

like a marionette, with the "string" connected straight to the brain. Will devices that read the output of neural signals ultimately be used to see into the mind and to read thoughts? These technological breakthroughs are not close enough to start changing policies and laws, but the technologies that are developing today foreshadow capabilities that could germinate societal fears now.

The clinical application of deep brain stimulation (DBS) technology for conditions such as Parkinson's disease, epilepsy, and severe depression is generally uncontroversial, as it provides patients relief from symptoms. Devices used for DBS today could be used in the future to transmit signals to regulate thoughts, moods, and behavior. The specter of mind control will surely haunt any device that promises such control of behaviors and thoughts.

Yet, these applications will likely arise initially to meet perceived societal needs. Neural implants for behavioral regulation could be used for those convicted of criminal behavior and mentally ill persons, much like electronic house-arrest bracelets for parolees. The public may actually desire this technology in the name of preserving public safety. Indeed, some criminal behaviors may ultimately be viewed as treatable medical conditions, benefiting the individual and society as a whole; but these applications will fuel debates by human rights advocates and by those who want to make sure that punishment – and not just correction – is meted out by the judicial system.

Involuntary use, mandatory sentencing, or coercive prescription of these technologies will trigger constitutional and human rights controversies, and they would likely be protested vigorously by advocacy groups (and contested legally). The efficacy of any these applications would have to be proven scientifically, but application of these technologies could have a major effect on the justice system.[67] Voluntary use in a medical or therapeutic setting will likely not raise constitutional questions, but these contexts may not allay public concerns about mind control, potential malfunction of the technology, and issues of responsibility, remuneration and care.

Mitigating fear about mind control revolves around distant technological capabilities and current speculations; it will be difficult to control. Military and governmental development of neurotechnology will inherently be suspect by the public and by human rights groups, since these technologies could be subject to misuse.[68]

- **Repair versus Augmentation**

There will also likely be public discomfort with non-essential or elective use of neurotechnology that, instead of repairing a damaged nervous system, augments normal capabilities.

Where is the line between bringing someone to normal functioning versus augmenting their normal capabilities? By sophomoric example, if "turning on the restore IQ machine" for five minutes brings an individual back to his "normal level," why not add a couple of minutes to make him a genius? Technologies that revive basic functionality to paralyzed patients or amputees would be relatively uncontroversial, and build on current advances in prosthetics and other assistive devices. However, many

67. Use of such devices as part of a convict's sentence might create a question of cruel and unusual punishment as a matter of first impression under the Eighth Amendment to the U.S. Constitution, though there may be applications of neurotechnology that are considered humane and effectual.

68. Racine E, Bell E, Illes J. Can we read minds? In: Giordano J, Gordijn B. (eds.) *Scientific and Philosophical Perspectives in Neuroethics*. Cambridge: Cambridge University Press, 2010, p. 244-270.

neurotechnologies could also be used to enhance a "normal" person's abilities. For example, cochlear implants in use today enable hearing-impaired people to regain normal function, but they also allow them to hear some sounds not audible for a person with "normal" hearing. There are also all the usual attendant biomedical ethics concerns (HIPAA, patient consent, appropriate use, end-of-life decisions, etc.) to consider in clinical and medical applications of these neurotechnologies.

There may be an ethical distinction between different types of augmentation, primarily based on purpose or extent, but the line is not necessarily clear. For example, augmenting cognitive function for learning, training or job performance purposes (i.e., a soldier who needs to quickly learn a language) may be acceptable, but cosmetic or elective augmentation may not.

- **Augmentation and Enhancement**

Augmentation and enhancement technologies can refer to biological intervention or the use of digital or mechanical devices, whether implanted or external. Enhancement of human capabilities may range from physical to cognitive aspects of human performance; given the roots of many technologies in restorative purposes it appears likely that these will be transitioned to be the forerunners of augmentation devices. Early forms of augmentation are also likely to develop from existing computing capabilities in learning and communication tools.

One of the thorniest issues in neurotechnology may be in the transition of technologies developed for medical and restorative purposes into use as enhancement devices. While the media often highlight fears that the technology could one day be used maliciously for mind control, a more immediate issue for public debate will be the use of these technologies for enhancement of cognition, memory or other brain functions by the military, professionals and others.

As the technology progresses, the possibility of enhancing memory, cognition, and experience will expand. Neurotechnologies that could have high public demand might include decision-making tools, learning and memory enhancements, and ways to enhance, record, or play back an experience. For example, researchers are currently developing brain interface technology to aid patients with memory loss, and are working to develop an artificial human hippocampus that would restore the ability to form new memories (not necessarily store new or existing memories); It is postulated that this will be available in the next fifteen to twenty years.[69] This sort of enhancement would certainly be in high demand even by "normal" people, to boost their memory function, as can be predicted by the booming market for natural compounds that claim to enhance memory.[70] As these technologies emerge and people begin to desire and demand them, serious ethical issues will arise, including access, fairness, and consent.

Social pressures will also affect the use of brain augmentation technologies. Parents could pressure their children to get enhancements to get better grades, make higher scores on entrance exams, and gain admission to higher ranked schools. Similar pressure to "self-medicate" is already demonstrated in students who seek out friends with attention deficit hyperactivity disorder (ADHD), so as to procure

69. Sandhana L. "Chips coming to a brain near you." *Wired.* October 22, 2004. http://www.wired.com/news/medtech/0,1286,65422,00.html.

70. Compounds used for memory enhancement, such as gingko bilboa, ginseng, and other herbs, had combined sales of $4.4 billion in 2005. See: Wright R. The Herbs and botanicals market: Returning to its roots. *Nutraceuticals World.* July/August 2006. http://www.nutraceuticalsworld.com/articles/2006/07/the-herbs-botanicals-market-returning-to-its-roots.php.

prescriptions for drugs such as Ritalin or Adderall, which are used to improve concentration and energy, and/or the use of brain-interface technologies to evoke similar ends.[71] High pressure professions and business could come to expect brain enhancement as the default standard.

These technologies may also create a divide that will in part depend on their social acceptance. Varying social acceptance of performance-enhancing pharmaceuticals by different populations in distinct contexts demonstrates the social and changeable nature of attitudes toward such enhancements. Ritalin is socially accepted for children who are determined to need it (the number of whom is continually increasing); stimulants are marginally socially accepted for professionals who just want to "get ahead"; and steroids and other performance-enhancing drugs are not socially accepted (and generally illegal) for professional athletes, but have widespread use nonetheless. It is likely that the range of neurotechnologies available in the future will span this spectrum of social acceptability and use, and in some cases they may be used regardless of social acceptability or legality.

The future availability of neurotechnology to the public for optional enhancements will raise fundamental issues of fairness and access that, while not unique to neurotechnology, will take on a new dimension when dealing with mental capacity and cognition. Cosmetic surgery, which is only affordable by a certain segment of the population, is also used for both clinical and elective purposes, but cosmetic surgery does not fundamentally alter one's capabilities.[72] Elective brain augmentation would change the proverbial playing field, and those who do not have the money to access it may be fundamentally disadvantaged.

Potential future neurotechnologies that boost intelligence, knowledge, and brain function will likely only be available at first to the wealthy, unless there is a conscious attempt to make it more widely affordable. Numerous competitive settings, such as academia, the job market and politics, would be skewed by unequal access to such technology. While access to technology in such settings is already slanted due to social, economic, racial, and other factors, neurotechnology could be radically different since it could significantly change mental capability. However, if the access issue could be overcome, the same technology could instead be a leveling influence, for instance by improving "normal" or below-average cognitive function for a large number of people.

Enhancement technologies are likely to be produced and promoted by private industry, which sees large potential profits in these technologies. As in stem cell research, privately-funded organizations can push research and development forward when government research is restricted by public resistance or demands for regulation that are not applied to private organizations. For these organizations, it is likely that either regulation or legal challenges will be the method for restricting activity, and it is quite possible that their activity will only be checked by fear of, or subjection to lawsuits.

Broader concerns about brain interfaces being used for enhancement may be addressed via scientific professional societies or journals, which can host debate within the scientific community about the guidelines that should be established for enhancement technologies. A national-level debate on

71. Giordano J, DuRousseau D. Toward right and good use of brain-machine interfacing neurotechnologies: Ethical issues and implications for guidelines and policy. *Cog. Technol.* 2011; 15(2):5-10.

72. Chatterjee A. Cosmetic neurology: The controversy over enhancing movement, mentation and mood. *Neurology.* 2004; 63:968–974.

appropriate use of enhancement technologies may be very productive in order to set policy, standards and guidelines that can be applied to private research and industry. Participants would include national funding agencies such as NIH and NSF, together with large research institutions, universities, and other sites of current research in neurotechnology, as well as cadre of devoted scholars in neuroethics. Establishing consensus within the community of researchers on what appropriate enhancement technologies might be is crucial to the ongoing self-regulation of the field, as the technology advances. A national study group could also serve to evaluate and determine policy on enhancement, as in The President's Commission for the Study of Bioethical Issues (formerly called the President's Council on Bioethics),[73] but steps should be taken to ensure that this process does not become too separated and distant from the actual community of researchers, and/or too highly politicized.

- **Human-Computer Interaction and Sentient Machines**

  "Cognitive computing" and "brain-based devices," computers modeled on patterns of human cognition may generate fears that such machines could become smarter or stronger than humans, or become sentient, independent beings. As people begin to rely more on increasingly complex and sophisticated devices (as cell phones, computers, and other tools that are used today), the devices may become more autonomous from the users' control, raising legal issues of accountability, fault, liability, and intellectual property. A common cultural reference point is HAL, from *2001: Space Odyssey*, who turns against his human operator. With sentient awareness comes the issue of control: Would these machines be considered a new life form? Would they have inherent rights? Will we always be able to turn them off? What would their role in society be? This human-computer interrelationship could lead to cyborgs, or human-machine hybrids or chimeras – some futurists and technophiles have declared cyborgs an ideal of human progress, but this remains contentious, and the general public is not likely to embrace this idea, at least in the near future.[74]

- **Equity, Fairness, Access**

  In health care, technology, education, and many other areas, social and economic factors have an impact on individual access to goods and services. Neurotechnology presents new challenges, however, in both access to technology and the way the technology is used. Like many other advanced technologies, it will initially only be available to a small number of people. Neurotechnology could fundamentally affect an individual's capabilities, by enhancing learning and cognition or regulating other brain functions. In aspects of access and applications, neurotechnology could significantly increase the gap between the so-called "haves" and "have-nots" in society.

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73. For example, see documentation provided by a previous Council: *Beyond Therapy: Biotechnology and the Pursuit of Happiness* (October 2003).

74. (a) Benanti P. The cyborg and cyborgization. In: Giordano J. (ed.) *Neurotechnology: Premises, Potential and Problems*. NY: CRC Press, 2012, p. 191-198. (b) Fukuyama F. *Our Posthuman Future*. NY: Farar, Strauss, Giroux, 2002. (c) Gray CR. *Cyborg Citizen*. London: Routledge, 2001.

- **Individuality and the Fundamental Essence of the Mind (What Does it Mean to be Human?)**

Neurotechnology is likely to be socially disruptive, even more so than nuclear technology and applied genetics, because it addresses the fundamental nature of who we are as human beings. Human nature, intelligence, consciousness, mental illness, the mind's relationship with the brain and body, and other aspects of brain function and potential will all be re-conceived.[75]

As research in neurotechnology advances, the subject of examining or altering a fundamental human characteristic is generating controversy, and some critics have already begun to raise these concerns.[76] Culturing or transplanting brain cells could be viewed as morally reprehensible or unethical, since the brain is seen as the fundamental essence of an individual, more so than other parts of the body. The aspect of human identity apparently multiplies public controversy in the area of medical and scientific innovation, as seen by the ferment caused by the face transplant in France in November, 2005.[77] The same will be true of neuroscience and neurotechnological research and interventions. The potential of scientific research to alleviate disease and disability will not trump the moral and religious concerns held by those who oppose those research techniques and translations that explicitly affect the brain and mind, and the implications of such interventions upon a definable self.[78]

The fundamental relationship of the brain to the mind, consciousness, and individuality may create some hurdles to neurotechnology research and results. Reductionist and scientific concepts of cognition, self-hood, thought, and emotion may fly in the face of strongly held religious and moral beliefs. As neuroscience research reveals the areas of the brain that support spirituality, religious behavior or character, and show religious belief or potential as a development of the brain, religious groups may raise concerns. The most immediate effect could be restrictions on funding or regulation of research.

Neurotechnology may be especially resisted for religious and moral reasons because it questions what it means to be human. This may be significantly more explosive and divisive than the debate over stem cell research. To probe or alter the "source code", memory, and functioning of a person's central nervous system will certainly generate vigorous resistance.

75. Benedikter R, Giordano J, FitzGerald K. The future of the self-image of the human being in the age of transhumanism, neurotechnology and global transition. *J. Futures*. 2010; 42(10):1102-1109.

76. Bailey R. "On human dignity: Will biotechnological progress lead to human degradation? Leon Kass thinks so." *Reason Magazine*. February 9, 2007. http://www.reason.com/news/show/118608.html.

77. "Woman Has First Face Transplant." *BBC News*. November 30, 2005. http://news.bbc.co.uk/1/hi/health/4484728.stm.

78. (a) Autiero A, Galvagni L. Religious issues and the question of moral autonomy. In: Giordano J, Gordijn B. (eds.) *Scientific and Philosophical Perspectives in Neuroethics*. Cambridge: Cambridge University Press, 2010, p. 134-145. (b) Jeannotte AM, Schiller KN, Reeves LM, DeRenzo EG, McBride DK. Neurotechnology as a public good. In: Giordano J, Gordijn B. (eds.) *Scientific and Philosophical Perspectives in Neuroethics*. Cambridge: Cambridge University Press, 2010, p. 302-320. (c) Siipi H. Is neuroenhancement unnatural, and does it morally matter? In: Giordano J. (ed.) *Neurotechnology: Premises, Potential and Problems*. NY: CRC Press, 2012, p. 199-212.

V. RECOMMENDATIONS

Neurotechnology currently encompasses a wide range of disciplines that are rapidly coalescing into a field of brain science. As scientists in disparate areas collaborate to advance understanding of the brain and the technologies used to interact with it, some major changes in the infrastructure of this research enterprise will be required. A government effort in this area will significantly affect the development of neurotechnology and of the scientific community that supports it. The Federal government is especially well-positioned to make a significant advance in this field, with existing programs in several areas related to neurotechnology, and the potential to jump-start several key technologies with focused investments.

Any government investment should build on ongoing work in neurotechnology, and a comprehensive investment and development strategy will be needed to help move neurotechnology forward. To achieve this goal, the study team offers recommendations below on key programs and research areas that should be pursued. We anticipate that these first steps along the Roadmap will lead to exponential gains in understanding of the brain, and to development of revolutionary neurotechnology applications.

Management and Programs

- **Create a focused program of neurotechnology investments on critical areas of the Roadmap.**

  There are many existing programs in neurotechnology and many other areas of science and technology that could be applied to neurotechnology research and development. A Roadmap for neurotechnology research will serve to coordinate and focus investments across government on enabling S&T and developing key applications. Coordination of program investments should also include facilitating communications among Federal agencies' programs on neurotechnology, ensuring that research efforts are targeted and efficient and avoid duplication.

- **Create new programs in neurotechnology and develop neurotechnology "Grand Challenges."**

  The U.S. government effort in neurotechnology should designate Grand Challenges in key areas of the Road Map needed to advance neurotechnology. Recommended programs are outlined below.

- **Establish Advanced Research Centers.**

  A priority program should be the establishment of regional, integrated research centers for neurotechnology. These centers should include state-of-the-art imaging and signal decoding instruments, with capabilities for multiple-modality studies. These centers should play a major role in data-sharing between new and existing sites, with networked data collection and analysis capabilities, and advanced bioinformatics networks. The centers should bring together interdisciplinary teams of researchers to generate new ways of solving problems and new approaches in research. In recent years interdisciplinary teams have been established at some universities and research institutes with great success, often combining expertise in fields ranging from applied mathematics to neurophysiology to robotics and computing.

The centers should be located in areas with high concentrations of scientists in order to attract highly qualified individuals. This approach has been proven successful in such areas as nanotechnology and advanced computing.

- **Develop new imaging, data collection and signals analysis tools.**

  There have not been any major advances or entirely new methods of collecting brain data in decades, and large-scale investments are needed to foster the development of entirely new imaging technologies. In particular, we can leverage the expertise of the National Labs and other government entities in engineering, computing, and signal analysis to develop a new generation of signal collection devices and technologies, targeted at understanding and decoding brain signaling.

- **Build programs to understand and exploit neurogenesis and plasticity.**

  Neurogenesis and brain plasticity will play a key role in future efforts to repair brain injury and dysfunction, but much is still unknown about how these processes work. As greater understanding is gained, we will be able to manipulate and exploit these processes for clinical, learning, and other purposes.

- **Establish programs to develop multi-scale neural models.**

  Government and industry expertise in advanced and cognitive computing should be leveraged to build macro-, meso-, and micro-level models of brain function. These models can then be integrated into a multi-scale, integrated, theory-based model of the brain and cognition.

- **Fast-track development of brain interface technologies.**

  It will be crucial to develop new brain signal input/output devices with greater scope and function. This program would include extending and refining existing technologies like deep brain stimulation, neural prostheses, and neuromodulators, as well as efforts to transition clinical devices to other uses, such as biofeedback mechanisms or augmentation.

- **Participate in establishment of a National Neurotechnology Initiative to coordinate Federal efforts in developing neurotechnology and provide funding for ELSI research.**

  An effort would be modeled on the National Nanotechnology Initiative (NNI) and would coordinate R&D programs and funding across Federal government agencies. As in the NNI and the Human Genome Project, research on ethical, legal, and social issues and responsible research and development of neurotechnology would be integrated with scientific research and supported with set-aside funds. The goal is not to be proscriptive or to impede neurotechnological research and development, but rather to define and plot the potential trajectories of this research and it uses (and potential misuses) so as to engender a stance of preparedness and develop working group(s) that are dedicated to the address, analysis, guidance and governance of NELSI through the informing and formulation of policy.

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Key Research Initiatives

Several areas of neuroscience research will play key roles in the future development of neurotechnology. Several existing technologies are being used despite a lack of deep knowledge about how they actually work. Greater understanding of learning and cognition, neurodevelopment and plasticity, neurogenesis, and the cognitive systems' architecture of the brain will contribute to further advances in neurotechnology. Some of these areas are already being pursued by NIH and NSF for clinical and academic purposes, and partnerships should be established among these agencies and others to fund targeted research in areas applicable to desired neurotechnology programs.

- **Fund research in learning, cognition, neurodevelopment, plasticity, and neurogenesis.**

  Greater understanding of the physiological bases of learning, cognition, neurodevelopment, plasticity, and neurogenesis will advance current efforts at enhanced learning and training methods, and will enable future research in augmenting human capabilities in these areas. NIH, NSF, and many other research institutes across the country have programs in these areas, and new programs should be established to target these research efforts at areas of cognition and neurodevelopment that are essential for further steps in neurotechnology. Greater understanding of learning, memory, adult neurogenesis, tissue and neuroengineering are all key areas. This research will also contribute to advances in the detection, prevention and repair of brain injury and treatment of neuropsychiatric disorders.

- **Fund research on cognitive systems architecture of the brain.**

  Research on the cognitive systems' architecture of the brain will rely on advanced modeling tools as well as deep understanding of the structure and function of the brain. Understanding in these areas will in turn be needed for more advanced areas of neurotechnology, such as augmentation or manipulation of brain signals and cognitive function.

- **Support or lead an effort to establish a national repository for neuroscience data.**

  The lack of compatible, easily accessed brain data was one of the most commonly cited impediments to research in the regional workshops conducted for the study. There are some existing, embryonic efforts at establishing national networks for data-sharing, in particular the NIH-sponsored BIRN. A broader Federal government research effort could support computing initiatives and provide incentives for researcher participation and data sharing. Regardless of the method chosen, the Federal government can play a pivotal role in building the computing and informatics tools needed to make simplified, standardized data-sharing a reality.

NELSI Recommendations

Neurotechnologies are developing so rapidly that government and private institutions may not be able to adapt adequately and promptly to the ethical, legal and social impacts incurred by the technology. Proactive steps should be taken to anticipate and mitigate these impacts. Otherwise, the technologies will have unintended deleterious effects, and the reaction to them could impede further development of the technologies for beneficial purposes.

Neurotechnology may be a highly controversial area of research. In particular, military and government work in these areas will always encounter some degree of resistance and distrust. There will always be tin-hat conspiracy theorists who think government agencies and/or the military is implanting chips in their brains to read their thoughts, or who will read devious intent into programs that the military or other agencies may view as non-controversial or necessary.

Thus, it would be prudent to make a conscious effort to address the potential for a major public outcry or movement before it emerges. The Federal government should make a substantive effort to pre-emptively address issues that may be of concern, since it is somewhat easier to prevent major public opposition than to refute it once it emerges. We have called for public education, openness and transparency about the purposes of research and applications as key to preventing small numbers of critics from developing into large-scale social movement, against government research efforts in this area, or against neurotechnology itself.

- **The Federal government research program in neurotechnology should take immediate steps to deal with NELSI issues.**

As the government formulates a strategic investment plan for neurotechnology, it should pay careful attention to NELSI issues. Primary areas of importance are to ensure coordination of neurotechnology efforts, develop a strategy for communications and public relations, and develop policy on ethical, legal and social issues.[79] A public website should publish general information on neurotechnology, as well as specific programs and areas of research, such as clinical applications, advanced prosthetics, brain injury repair, advanced computing, development of new diagnostic capabilities, basic research, etc.

Government research programs should strive for openness and transparency whenever possible (though there will, of course, be some projects that need to be classified for national security reasons). Opposition to stem cell research and the use of neurotechnologies in deception detection technologies are some of the most immediate and volatile concerns, that could negatively affect all areas of neurotechnology research; research programs should be aware of this concern and take preventive actions.

79. (a) Giordano J, Olds J. On the interfluence of neuroscience, neuroethics and legal and social issues: The need for (N)ELSI. *AJOB-Neuroscience.* 2010; 1(2):13-15. (b) Giordano J, Forsythe C, Olds J. Neuroscience, neurotechnology and national security: The need for preparedness and an ethics of responsible action. *AJOB-Neuroscience* 2010. 1:1-3. (c) Gini A, Rossi J, Giordano J. Considering enhancement and treatment: On the need to regard contingency and develop dialectic evaluation. *AJOB-Neuroscience.* 2010; 1(1):25-27. (d) Giordano J, Akhouri R, McBride DK. Implantable nano-neurotechnologies: Ethical, legal and social issues. *J Longterm Effects Med Implants.* 2009; 5(9):45-54.

- **Work with outside experts in industry and academia and form partnerships between agencies to prepare for and deal with potential issues.**

  Government efforts in neurotechnology should form partnerships across relevant agencies, to include NIH, NSF, DOD, and the VA, to address NELSI issues. Outside expertise from industry and academia should be sought to ensure the responsible development of neurotechnology and to ensure that any/all policy developed has input from the community of stakeholders.

- **Develop neuroethics policies and standards for research and application of neurotechnologies; research guidelines should include procedures for ethical review of study design and research objectives.**

  The Federal government should develop policy and guidelines (or best practices) on research and application of neurotechnologies, and commit to the responsible development of neurotechnology. Guidelines and policy are needed immediately for near-term, volatile issues like the use of neurotechnology for deception detection, and neural stem cell research. Specific research standards need to be established for these neuroethical, legal and social considerations, just as they have been in areas such as genomics and nanotechnology. Also needed is an evaluation of current procedures for ethical review of design and research objectives of studies engaging neurotechnologies, such as the Institutional Review Board and Data Monitoring Committee systems currently used for human subjects research, to determine whether additional considerations are needed given the cutting-edge and often socially contentious nature of this research. The development of these guidelines and policies would benefit from input from ethicists, lawyers, and other outside experts.

- **Allot specific funding for NELSI, including devoted professional staff (or contractors), following the DOE, NIH, and Human Genome Project models of directed funding for research studies and staff hours devoted to ELSI.**

  The Federal government neurotechnology investment effort should include devoted professional staff (or contractors) for NELSI, and include reserved funding for NELSI in neurotechnology-related program budgets. Existing models have been demonstrated by DOE, NIH, and the Human Genome Project, which have Congressionally-mandated set-aside funding for research studies and staff hours devoted to ELSI. Making budgetary allowances for a voluntary set-aside of NELSI-specific funds will help programs prepare for public questioning of their programs and demonstrate dedication to the responsible development of neurotechnology.

  Neurotechnology programs should also designate a staff member responsible for public information and relations, media, and legislative relations related to neurotechnology. Neurotechnology-related press releases, Broad Agency Announcements (BAAs), Requests for Proposals (RFPs), etc. should be vetted through this staff before release to ensure clarity, verify adherence to ethical research guidelines, and promote sensitivity to public concerns.

- **Focus early efforts on short-term goals and prevent over-stating of objectives or technical possibilities.**

  Early public efforts in neurotechnology should be focused on short-term, realistic goals of clinical applications, prosthetics, treatment and repair of brain injury, diagnostic tools, cognitive computing, modeling and analysis tools, etc. Researchers should communicate clearly what work is being done and be careful not to overstate their research and/or submit to amplified claims of potentially beneficial or harmful effects.

- **Carefully construct a communications and public education strategy to address neurotechnology-related ethical, legal, social, and political issues, and to engage civil-libertarians, legal, and ethical scholars.**

  Public dialogue and education will be essential to promote public understanding of neurotechnology. This dialogue and dissemination of information should include legislators and policy makers so that they can make decisions using the best available science and without miscommunication, misinformation or misuse of available information. The scientific and research communities must engage in an active dialogue with Congress and Congressional staffers on neurotechnologies, the benefits, burdens, risks and potential harms of such neurotechnologies, and why continued research is important.

  A major public effort will be required to increase public understanding of neurotechnology and to address neuroethical, legal and social issues that may arise as the public learns more about these emerging technologies.

  While there may be a need for secrecy in some projects (namely, those that are focal to high level national security and defense), public knowledge and opinion of neurotechnology applications needs to grow along with the development of the technology. Public information and education is essential, and the scientific community, foundations and government should use many methods to get reliable information into the press and media. Many current applications of neurotechnology are of great public interest and are likely to be favorably received, such as assistive devices, brain injury repair, and restoration of cognitive function to paralyzed or injured patients.

  In addition, military and governmental development of neurotechnology may raise public concerns about the potential for misuse. Maintaining openness about neurotechnology may help prevent potential surprise, and embarrassment if and when military or government work in neurotechnology is exposed by advocates in the name of public interest.

  The Federal government should engage in proactive public education efforts across relevant agencies. Scientific associations, foundations and governmental entities such as NSF and NIH should hold the role of promoting public education and information on neurotechnology. These efforts may include science programming (i.e., *NOVA*, *Discovery*, *Science*, *Nature*, etc.), popular media, internet resources, and public forums. Such an effort could include creating a program to engage scholars in law and the humanities at the university level or via public forums.

  These public and popular press forums, guided by scientific expertise, will help ensure a balanced discussion of neurotechnology. The many positive potential applications of neurotechnology for repairing damaged nervous systems, improving prosthetics, and enhancing soldiers' performance on the battlefield, provide easy stories to tell about benefits of pursuing a dedicated agenda of neurotechnology research and development. Agencies developing neurotechnologies have good reason to publicly emphasize the positive aspects of potential medical breakthroughs in the treatment of brain injuries, neurodegenerative diseases, and neuromotor dysfunction. However, emphasis on the beneficial results promised by this research will not quell all concerns about neurotechnology, especially future applications like augmentation and military use. Positive publicity should not be relied upon to gloss over the serious ethical, legal, and social issues that may arise with this technology and which should be exposed to public debate.

- **Educating and communicating research and findings to legislators and the public is essential to mitigate potential concerns.**

  Legislators, staffs and policymakers should be kept informed of neurotechnology research, including development of the technology, the probable benefits, possible impacts, and potential issues of importance to the public. Updates should emphasize, however, the importance of neurotechnology research to future military and capabilities, such as brain repair for the disabled and severely injured military members, enhanced battlefield mental capability, and other tools that are of importance for national security and public health. Legislative relations are another key tool in ensuring that public concern or opposition to certain aspects of neurotechnology do not dominate or overpower discussion of the important benefits of neurotechnology.

- **Support a review of existing protections and laws for neurotechnology applications, including civil liberties, medical information, employment, discrimination, guarantees of privacy, federal regulation of devices, etc.**

  A framework of protections and regulations regarding lie detection using polygraphy already exists, but active engagement is needed to extend these protections to the use of neuroimaging for deception detection. New laws may be needed to help ensure appropriate use of neurotechnology and to prevent future legal and legislative crises. Proactive engagement will have the dual benefits of protecting individual rights and forestalling legal contests, which could impede the development of the technology.

  As brain augmentation devices and applications develop, privacy and security protections and laws for the devices, archives, data and perhaps thoughts themselves will have to be examined and developed as well. It is possible that existing frameworks for privacy, medical data, and information security can be extended or modified to incorporate this category of neurotechnologies. However, a review of the current legal and regulatory framework will be needed.

  A possible mechanism for this review would be a panel made up of legal experts, ethicists, scientists, and representatives from advocacy groups most likely to contest use of the technology (i.e., ACLU), as well as representation by professional societies (of attorneys and scientists), and members of the judicial system.

  This review panel would be charged with formulating specific recommendations on possible extensions of existing law concerning civil liberties, medical information, employment, discrimination, guarantees of privacy, etc. This discussion should include the Federal Rules of Evidence, the Federal Rules of Civil Procedure, and the *Daubert* line of cases regarding expert testimony. Some of the laws that should be reviewed and potentially extended to cover neurotechnology applications include EPPA, HIPAA, GINA, ADA, Title VII of the Civil Rights Act (for employment discrimination purposes), and other federal discrimination and privacy statutes. Issues reviewed should include use of neurotechnology for deception detection by government and other employers, and in the workplace in general, for such purposes as alertness monitoring, placement, evaluation, etc. In addition, judicial conferences should be held to educate legal practitioners on the development of neuroimaging technology for deception detection and the differences between neuroimaging and polygraph examinations that could arise if expert testimony were offered in court.

Fear of unauthorized use by private companies or the government is at the root of much of the potential opposition to neurotechnology. To prevent such abuses of neurotechnology, the U.S. Congress should consider outlawing or regulating the remote and surreptitious use of neuroimaging (and perhaps neurogenetics), even if the development of such capacity is not imminent. Existing Constitutional principles of privacy and protection from government intrusion provide a framework and precedent for these regulations.

Government regulation and approval of brain implants, external interventions and augmentation will help mitigate concerns about safety. Scientists and neurotechnology developers hold legitimate reservations about federal lethargy obstructing or inhibiting research, development and fielding of these devices, but either the FDA or some other agency will need to have purview over this area. The agency should be spurred to anticipate developments and have necessary expertise and guidelines in place. In areas such as military research, where FDA regulations may not come into play until technologies are further developed, safety and security concerns will need to be explicitly and openly addressed via an internal oversight mechanism and established policy, such as an Institutional Review Board process.

- **Participate in developing model policies and procedures for appropriate use of neurotechnology, in consultation with outside experts, professional societies, and government agencies.**

Government agencies should work together with scientific professional societies to establish standards for research and applications of neurotechnologies. The NNI and the Human Genome Project provide positive examples of unified Federal research and inter-agency cooperation on the societal effects of emerging technologies. These programs have combined research into the ethical, legal, and social effects of technology with scientific research, and allayed some societal concerns by addressing them early on.

Guidelines for responsible neurotechnology development may be formulated by scientific societies or a government-led consortium of relevant experts, as demonstrated by the NNI, the Human Genome Project, and the National Academies' committee on stem cell research. Participation of the scientific community in developing guidelines for development and applications is essential to ensure that important research is not limited, and to encourage compliance by the scientific community. This engagement would provide a professional forum for measured dialectic on issues fostered by neurotechnological research, development and potential uses. The guidelines developed should include both procedural planning and sensitivity to ethical issues in research and development of neurotechnological applications.

A potential mechanism to facilitate this interaction would be to establish a dedicated working group or commission on neurotechnology and the neuroethical, legal and social issues fostered by these technologies, which would draw on partnerships or working relationships with other government and military agencies as well as various professional associations.

This panel should develop model policies and procedures for appropriate research and use of neurotechnology, in consultation with outside experts in ethics, law, civil liberties, etc. These model policies could be adopted by the government, military, academic, and private entities that will be involved in developing applications for neurotechnology. Establishing guidelines for responsible use can help ensure that neurotechnologies are studied, developed and used within ethico-legal bounds; these policies could roughly be called a "Handbook for Appropriate Research and Use of Neurotechnology." Guidelines on responsible research and development should be continually reviewed and adapted as new technologies emerge. Development of public guidelines for responsible use of neurotechnology could reduce liability in case of misuse, and may protect researchers in the future.

- **Facilitate or advocate the creation of oversight mechanisms to ensure appropriate and responsible research, development, and application of neurotechnologies.**

As the scientific and ethics communities work together to establish a set of guidelines for neurotechnology research and development, they should also establish an oversight structure at the institutional and national levels that can be internationally engaged to promote that neuroethical, legal and social concerns are appropriately and adequately addressed. This system would not replace traditional ethical review structures such as Institutional Review Boards, but instead would embellish upon their charge so as to more accurately focus neuroethico-legal review of key issues arising in and from neurotechnological research and use. These panels and advisory groups could be integrated with federal regulatory agencies' approval processes and other established oversight procedures. Such an oversight system could help allay institutional risk and fears of pursuing neurotechnology, and provide a national, standardized, public forum beyond the court system and Institutional Review Boards. The existence of a framework of guidelines and oversight may salve, to some degree, public or legislative concerns that the technology was progressing in ways that are out of control.

Since 2008 the Potomac Institute for Policy Studies' Center for Neurotechnology Studies has been dedicated to identifying and defining the moral, legal and social dimensions of new neuroscientific techniques and technologies. In this pursuit, the Center for Neurotechnology Studies has held 17 symposia and lectures and 4 national-level conferences, generated 34 academic papers, 12 book chapters and 5 major books in the international peer-reviewed literature, and provided 90 invited and plenary lectures at conferences, meetings, and symposia at a variety of national and international academic and governmental institutions.

	Immediate	Short Term	Long Term
Internal	• Establish research focus area on Neurotechnology • Build "Neurotechnology 101" website outlining current efforts and why they are important to our soldiers, national security, science and medicine • Establish long-term policy/ strategy for addressing ELSI issues • Develop internal policies and procedures on research and application of neurotechnology, especially for near-term issues like deception detection and stem cell research	• Make some budgetary allowance for set-aside funding (staff, studies, etc.) to address these issues • Implement policies on near-term, volatile issues such as deception detection and stem cell research, tie-in with communications, public relations, and legislative relations staff	• Evaluate current work in neurotechnology, lessons learned on ELSI, and establish strategy for next five years • Continue to evaluate and update internal policies and procedures for neurotechnology research
External	• Develop partnerships/ working relationship with other government/military agencies, professional scientific associations, advocacy groups, legal and ethics experts, and others • Participate in establishing a Panel or Conference on neurotechnology and ELSI issues	• Coordinate development of model policies and procedures for neurotechnology research, guidelines for responsible and appropriate research and use of technologies	• Government agencies conducting neurotechnology research and development should adapt and implement model policies • The Panel should continue to develop model policies as neurotechnology evolves

FIGURE 12: ELSI RECOMMENDATIONS.

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VI. CONCLUSIONS: THE NEUROTECHNOLOGY REVOLUTION

Part of the difficulty in Roadmapping future technologies is the idea of a destination. The possible paths for neurotechnology, and where they might lead, are not certain and may vary widely from what we have outlined above. But from our vantage point today, widespread use of some forms of neurotechnology is imaginable in the near future, and we can lay out the necessary first steps.

Overall, "Track 1: Fundamental Science" will feed into "Track 2: Technology and Applications" and vice-versa; progress of the two tracks is inter-related and interdependent. Progress in fundamental science will lead to development of technology and applications, and development of applications will drive new efforts in basic research. Together these tracks lead to the neurotechnology revolution in industry, commerce, computing, medicine, and perhaps life as we now know it. The U.S. government has a major role to play in moving this technology forward.

Building this Roadmap will necessitate identification of long-term goals, but there are some key elements of the Roadmap that will be needed regardless of the ultimate goals of developing neurotechnology. Complementing and augmenting human capabilities is a primary goal, and may be possible in a simple, noninvasive form in the near term. Brain interface technology and understanding of the brain will drive possibilities for augmentation and other applications. The best brain interface technology today is in clinical areas, but these could be rapidly improved, expanded, and transitioned to other applications. In addition, any physically induced augmentation will require sophisticated understanding of the neural processes involved in cognition, emotion and behavior to prevent adverse consequences and to enable comprehensive simulation before actual human trials are attempted.

Reducing the anticipated negative impacts of neurotechnology and alleviating public fears will require a strategic plan for mitigation, information dissemination, and action. This should include addressing the impacts and fear of the research itself, as well as the effects of future technologies. Both nature and government abhor a vacuum. Where there is no governance or oversight, public concerns, whether founded in fact or not, will motivate reactionary legislation or regulation.

The area of neurotechnology most likely to emerge soonest in the public arena is deception detection. Neuroimaging technology is rapidly maturing, even if its use for this purpose is not, and commercial companies are anticipating the need for these services now. In the next several years, neuroimaging for deception detection will knock on the courtroom door, with all of the ethical, legal, social and political impacts described in this report. Neuroimaging for employment and business purposes will be in demand. Technology developers should engage with policy-makers, advocacy groups and other stakeholders to logically extend the existing framework of protections to avoid adverse impacts while still promoting research and development of neurotechnology.

The inequities which will arise from brain augmentation and the enhancement of brain function will be difficult to mitigate until the extent of such new capabilities become apparent. At one point in time, the use of scientific calculators during exams or college entrance testing would have been considered cheating. The calculators were expensive. Now they are affordable, and the use in testing is accepted and sometimes prescribed. As devices and enhancements reach technological maturity and facile deployment in the marketplace, the questions of legitimate and ethical use, fairness and access should be anticipated and the engagement plans discussed above should be employed in a similar fashion. The first use of brain enhancement for elective purposes will most likely come from technology that was developed for brain repair, and the leap from medical and restorative purposes to elective ones to enhance competitive edge could come suddenly.

Public fear of new technology is not specific to neurotechnology. These fears have been the fuel for science fiction writers and Hollywood movies for decades, even though the fears may seem overblown or scientifically groundless. Nevertheless, neurotechnology will incur significant ethical, legal and social impacts. Neurotechnology's relationship to and effects upon the brain and the fundamental essence of personhood will make it a unique issue in the public eye.

It must be remembered, however, that these technologies hold tremendous promise for good. The proper framework of policies, laws, and regulation, can ensure that neurotechnologies yield many benefits while minimizing any potentially negative impacts. Past experience has shown that a proactive plan of information and engagement can promote technological advancements, secure the benefits of research, and avert adverse public reaction. We will need to anticipate potential future issues, and develop practices and policy to address them, so that we won't be blindsided as they emerge. As in other areas, policymakers and the scientific community must balance the desire to bring about new technology with public concerns over the potential negative uses that such progress could evoke.

VII. APPENDICES

Appendix 1. Study Process

- **Extensive Research**
- **Regional Workshops with Experts in the Field**
  - Boston, Massachusetts
  - Albuquerque, New Mexico
  - San Diego, California
  - Arlington, Virginia
- **Briefings and Report of Findings and Recommendations**

The goals of this study were to develop a potential Roadmap for neurotechnologies with the most likely path or paths of development, identify key investment points and technical challenges, and analyze the potential impacts of this emerging technology.

The process for the study involved both in-depth research and analysis by the Potomac Institute study team and a series of four regional workshops. The study team met weekly for several months to generate an initial Roadmap, and then gathered input from major practitioners in neurotechnology from across the country. In these workshops, scientists were asked to envision the future of the field and what would be needed to move it forward significantly. These workshops were conducted in Albuquerque, New Mexico; Boston, Massachusetts; San Diego, California; and Arlington, Virginia. The participants represented universities, national laboratories, privately funded research institutes, clinicians, military scientists, government contractors, and industry. The Washington, D.C. area workshop was focused on ethical, legal, social and political issues, and included experts in civil liberties, bioethics, law, and public policy.

Appendix 2. The Potomac Institute for Policy Studies

OUR MISSION

The Potomac Institute for Policy Studies is an independent 501(c)(3), not-for-profit public policy research institute. The Institute identifies and aggressively shepherds discussion on key science and technology (S&T) issues facing our society, providing, in particular, an academic forum for the study of related policy issues. From these discussions and forums, we develop meaningful science and technology policy options and ensure their implementation at the intersection of business and government.

OUR PHILOSOPHY

The Potomac Institute is based on two basic principles. The first is that we fiercely maintain objectivity and credibility, remaining independent of any Federal or state agency and owing no special allegiance to any single political party or private concern. Our second principle is that we seek extensive collaboration with similar organizations, as well as with industry, academia, and the government, including the U.S. Congress and the Executive Branch. We believe that the study of today's complex issues demands a wide variety of contributions from various perspectives.

AREAS OF RESEARCH

The Institute's current endeavors have required the formation of special efforts in:

- Terrorism and Asymmetry
- National Security
- Science and Technology Forecasting
- Emerging Threats and Opportunities
- National Health Policies

The Potomac Institute has conducted studies on issues ranging from defense acquisition reform, dual use technology, weapons of mass destruction, national security, technology transition, all aspects of terrorism, to space commercialization. The Institute focuses on the implications of technology on society, government, and business. This includes the effects of government technology policies that have enormous consequences for our nation's growth and security. The Institute also supports critical national programs, including evaluating and developing Federal information technology policy and research and development investment options, analyzing military capabilities, exploring emerging threats and opportunities, evaluating and implementing effective technology transition, managing Federal technical programs, developing operational concepts, and assisting in long-range planning.

The Institute has conducted studies and provided support to the U.S. Congress, the Administration, the Department of the Navy, the U.S. Marine Corps, the National Science Foundation, Defense Advanced Research Projects Agency (DARPA), the Office of Naval Research (ONR), the National Aeronautical and Space Administration (NASA), private foundations, and several leading industries.

Appendix 3. The Center for Neurotechnology Studies

MISSION

The Center for Neurotechnology Studies (CNS) is an academic research center within the **Potomac Institute for Policy Studies.** The CNS pursues a four-part mission:

- Advocate and support the responsible development of Neurotechnology;
- Provide support to government agencies pursuing Neurotechnology by providing expertise in ethical, legal, and social issues, and develop policy options to address them;
- Anticipate ethical, legal, and social issues associated with emerging Neurotechnology, and shepherd constructive public discourse to address such issues; and
- Consistent with Potomac Institute methodology, the CNS maintains a standing in the scientific community by actively participating in the science itself.

The work of the Center is guided by an advisory board made up of experts in science, technology, ethics, law, and society.

SUPPORTING RESEARCHERS AND POLICY-MAKERS

The Center for Neurotechnology Studies will provide a neutral, in-depth analysis of matters at the intersection of neurotechnology and public policy. It will provide a forum for reasoned consideration of these issues by subject-area experts, policy-makers, and the public. The Center will cultivate knowledge and shepherd discussion on the implications of neurotechnology in legislative, administrative, regulative, judicial, academic, and entrepreneurial enterprises. In turn, the Center will become a highly-sought partner by the research community for advice, partnership, and advocacy for the public and private funding of key neurotechnology research.

ACTIVITIES

The Center actively shepherds public debate on neurotechnology, in addition to advising public and private developers of this technology.

- **Events:** The Center hosts a continuing series of lectures, seminars, and other forums to address all issues around the development of neurotechnology.
- **Publishing:** CNS publishes articles on all aspects of neurotechnology in both specialized journals and the popular press. This contribution to public debate will contribute to public understanding and help shape a reasoned and productive public dialogue on these issues.
- **Research:** The Center participates in neurotechnology research, particularly as it relates to policy and social change.

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